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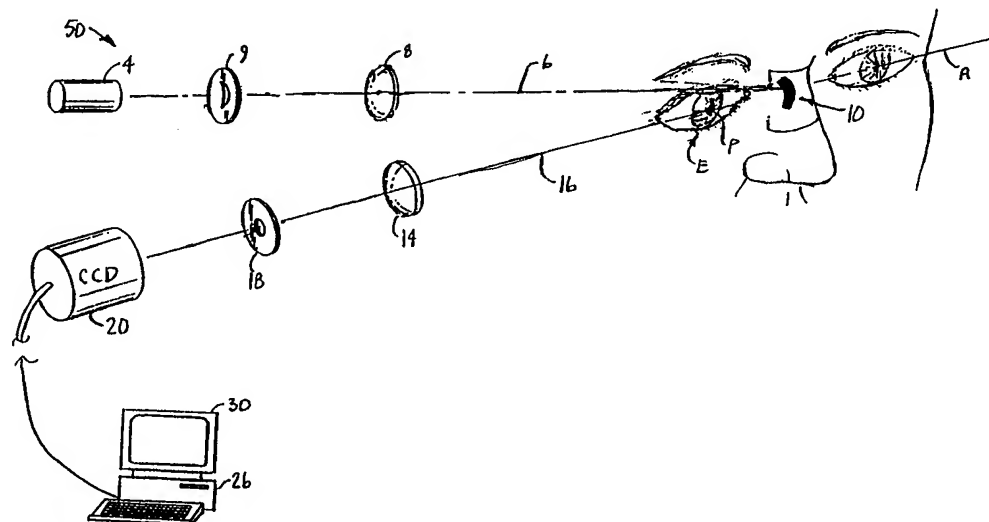
(57) Abstract

    Systems, methods and apparatus for generating images of portions of the patient's eye (E), such as the anterior surface of the
cornea. The methods and apparatus of the present invention are particularly useful for directly imaging the profile of the ablated region
of the cornea during or immediately following a laser ablation procedure such as photorefractive kerat–ometry (PRK), phototherapeutic
keratectomy (PTK), laser in situ keratomileusis (LASIK) or the like. These methods and apparatus allow the surgeon to precisely image the
exterior edge of the eye to characterize the profile of ablated corneas and to determine the spatial variance of tissue ablation rates during
the surgical procedures. Methods and apparatus are also provided for generating one or more images (4, 20, 30, 26) depicting the profile
of the ablated region of the cornea. The profile is registered with a pre–ablation profile to provide feedback regarding the true ablation
properties of the eye. This feedback permits the laser system to be programmed with a laser ablation algorithm based on the measured
ablation properties of the eye.

SYSTEMS AND METHODS FOR

IMAGING CORNEAL PROFILES

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of, and claims priority from, U.S. Patent Application No. Unassigned, filed May 22, 1998 (Attorney Docket No. 18158-000110), which is a continuation-in-part of U.S. Patent Application No. 08/863,665, filed May 27, 1997, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to systems, methods and apparatus for imaging and ablating surface contours. In particular, the invention relates to methods and apparatus for generating direct images of the anterior region of the eye. The present invention is particularly useful for generating silhouette images of the ablated region of the cornea during or immediately following a laser ablation procedure, such as photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK), laser in-situ keratomileusis (LASIK) or the like. The silhouette images include ablation profiles of the cornea that can be used to refine laser ablation procedures by tailoring the ablation process to match the actual ablation properties of the human eye.

Ultraviolet and infrared laser based systems and methods are known for enabling ophthalmological surgery on the external surface of the cornea in order to correct vision defects. These procedures generally employ an ultraviolet or infrared laser to remove a microscopic layer of an anterior

stromal tissue from the cornea to alter its refractive power. In ultraviolet laser ablation procedures, the radiation ablates corneal tissue in a photodecomposition that does not cause thermal damage to adjacent and underlying tissue.

5   Molecules at the irradiated surface are broken into smaller volatile fragments without heating the remaining substrate; the mechanism of the ablation is photochemical, i.e. the direct breaking of intermolecular bonds. The ablation penetrates into the stroma of the cornea to change its contour

10 for various purposes, such as correcting myopia, hyperopia, and astigmatism.

In such laser based systems and methods, the irradiated flux density and exposure time of the cornea to the laser radiation are controlled so as to provide a surface

15 sculpting of the cornea to achieve a desired ultimate surface change in the cornea. To that end, ablation algorithms have been developed that determine the approximate energy density that must be applied to remove a certain depth of tissue from the cornea. At ultraviolet wavelengths, for example, an energy

20 density of 1 joule/cm^2 will typically ablate corneal tissue to a depth of about one micron when applied in a series of pulses of about 100 to 400 millijoules/cm2. Accordingly, the ablation algorithms are tailored for each procedure depending on the amount and the shape of corneal tissue removal required to

25 correct the individual refractive error.

Although present laser ablation algorithms are relatively accurate, many of these algorithms assume that tissue ablation is uniformly related to irradiance within the treated zone. Recent studies of corneal topography following

30 PRK, however, have determined that, in some instances, there is a central area of undercorrection called a "central island" for large diameter areas of cornea exposed to a uniform laser irradiance. The term "central island" is generally defined as a central area of corneal ablation that appears to be

35 flattened less than the surrounding ablated area. In contrast to central islands, central overcorrection and peripheral undercorrection within the ablation zone have also been reported following PRK procedures. See e.g., Lin DDTC, et al.

Corneal Topography Following Excimer Photorefractive Keratectomy For Myopia. J. Cataract Refract. Surg. (1993) **19:149-154**. Although mild central topographic changes may not have a large bearing on visual function, some patients with clinically significant central islands can experience visual abnormalities including reduced best corrected visual acuity, monocular diplopia and image ghosting.

Investigators have studied modified ablation algorithms as methods to improve the quality of patient vision and post operative corneal surface. *See e.g.*, Seiler T., et al., *Complications of Myopic Photorefractive Keratectomy with the Excimer Laser.* Ophthalmol. (1994) **101:153-160**. It is believed that some common surface abnormalities (such as central islands) may be at least partially corrected by changing the ablation algorithm. For example, the ablation algorithm may be altered to provide additional laser pulses centrally to offset the effects of central islands.

Currently, the accuracy of modified ablation algorithms is determined from experimental ablation data and post-operative clinical data based on topographic measurement of the healed corneal surface. The healed cornea, however, has been covered by tear films and an epithelium layer with an average thickness of 50 μm. Consequently, topographic measurement of the healed anterior corneal surface after the laser ablation procedure may not accurately portray the true shape of corneal ablations. Accordingly, direct measurement of the ablated corneal surface would be extremely desirable (if not necessary) to understand the effects of changes to laser ablation algorithms on the ablated corneal shape.

Corneal topographic analysis using photokeratoscopic or videokeratographic methods provides objective measures of the quality of the healed anterior corneal surface following ablation procedures, such as PRK, PTK and the like. Current measurement devices, termed videokeratoscopes or corneascopes, typically employ several concentric rings or multiple discrete light sources to reflect a luminous object of known dimension from the cornea. The size of the cornea-reflected images of this object are then measured with photographic or electro-

optical recording methods to compare the shape of the cornea with a theoretical spherical shape. If the cornea is spherical, for example, the reflected images of these ring-shaped objects are equally spaced, continuous, concentric ring-shaped patterns. If the cornea has surface defects, or is not precisely spherical, the resultant ring images will be less equally spaced, or they will have a different shape, e.g., elliptical.

One of the drawbacks with many current methods of topographic analysis is that these methods typically treat the cornea as a close approximation to a convex sphere, and they require a specularly reflecting surface. Since the cornea is not precisely spherical, the results of the measurement generally depend on where the non-spherical cornea measurement is taken. Moreover, the corneal surface is not specularly reflective immediately following a laser ablation procedure, such as PRK. Another drawback is that videokeratoscopes do not measure the actual cornea topography, but merely measure the "average" radius. The central few millimeters of the cornea, which is very important optically, cannot be directly evaluated with these devices. Another drawback with these methods is that they are not capable of precisely measuring extremely small surface changes on the anterior corneal surface, e.g., on the order of 20 microns or less. The non-uniform spatial distribution of tissue ablation in laser procedures, however, is generally on the order of about 5-10 microns or less (i.e., about 10-20 percent of the intended ablation depth). Therefore, current methods of topographic analysis are not as accurate for measurements of the spatial variation of tissue removal as one would desire.

It would also be desirable to accurately measure the shape of the ablated region of the cornea during or immediately following the ablation procedure (i.e., prior to healing of the corneal tissue and regrowth of the epithelium layer). This would allow a direct measurement of the ablated surface without the tear films or the epithelium layer interfering with the accuracy of the measurement. In addition, this would allow the surgical team to characterize the profile

of ablated corneas and to determine the spatial variance of
tissue ablation rates during the surgical procedure, which may
afford the opportunity to provide in situ feedback to the
surgeon.

5   Unfortunately, it is extremely difficult to
accurately measure the ablated surface of the cornea during or
immediately following a surgical procedure with current
techniques. One reason for this difficulty is that the
epithelium is removed from the cornea prior to PRK to expose
10   the diffusely reflective stromal corneal surface. Thus,
keratometry techniques based on reflection are unsuitable.
Moreover, although corneal topography utilizing
videokeratography can be performed immediately after PRK when
artificial tears have been instilled, it is the shape of the
15   tear film and not the ablated cornea which is measured. In
addition, the use of corneal topography techniques to assess
the acute shape of PRK ablations also suffers from the
inability of these instruments to accurately measure surfaces
with an abrupt change in curvature.

20   Projective techniques utilizing rasterstereographic
imaging such as the PAR Technologies Corneal Topography System
(U.S. Patent No. 4,995,716) have been used on deepithelialized
and freshly keratectomized corneas. These rasterstereographic
systems project a grid on the cornea which is then imaged by a
25   video camera, digitized and analyzed to produce a tabulation
of corneal elevations versus corneal diameters. Since the
cornea is a transparent member which is non-diffusing to
light, however, a grid projected onto the cornea is not
sufficiently visible. Thus, a diffusing material, such as
30   talcum powder or a liquid film of fluorescent dye, is
typically applied to the cornea to provide a surface on which
an image can be visualized. These powders or films degrade
the accuracy of the measurement because it is the shape of the
powder or film (and not the cornea) that is measured.

35   What is needed, therefore, are improved methods and
apparatus for measuring the outer profile of the eye. In
particular, these methods and apparatus should be capable of
directly measuring the depth of corneal ablation to the order

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of about 5.0 to 10.0 μm or less in order to evaluate the
spatial variance of tissue ablation rates. Further, it would
be particularly desirable if these methods and apparatus were
capable of directly measuring the ablated region of the cornea
5   during or immediately following the laser ablation procedure
to provide an accurate profile of the ablated corneal surface
(without adding a liquid film or powder to this surface).
Such information may be used to modify the ablation algorithm
based on differences between the theoretical and directly
10   measured ablation profiles.

SUMMARY OF THE INVENTION

       The present invention is directed to systems,
15   methods and apparatus for generating images of the eye, such
as the anterior surface of the cornea. The methods and
apparatus of the present invention are particularly useful for
directly imaging the profile of the ablated region of the
cornea during or immediately following a laser ablation
20   procedure, such as photorefractive keratometry (PRK),
phototherapeutic keratectomy (PTK), laser in-situ
keratomileusis (LASIK) or the like. These methods and
apparatus allow the surgeon to precisely image the exterior
edge of the eye to characterize the profile of ablated corneas
25   and to determine the spatial variance of tissue ablation rates
during the surgical procedures. In an exemplary embodiment of
the present invention, methods and apparatus are provided for
generating one or more images depicting the profile of the
ablated region of the cornea. The profile is registered with
30   a pre-ablation profile to provide feedback regarding the
ablation properties of the eye. This feedback permits the
laser system to be programmed with a laser ablation algorithm
based on the measured ablation properties of the eye.
       In one aspect of the invention, a method is provided
35   that includes projecting light against a surface adjacent to
or near the eye and reflecting the light from the surface
across an anterior region of the eye. A portion of the
reflected light is received by a photodetector, such as a

charge coupled device (CCD), and the corresponding signals are processed to generate a high contrast silhouette image of the anterior region of the eye. The silhouette image includes a dark portion representing the light that is occluded by the

5   cornea and a light portion representing the light that passes across the eye. The light and dark portions define a high contrast line therebetween that represents the profile of the cornea. Providing a direct, silhouette image of the front edge of the eye improves the resolution as compared to

10   previous methods that approximate the corneal profile based on measuring reflected light patterns. For example, the silhouette image generated by the present invention has sufficient data points to minimize smoothing or approximation of the line, which provides a high resolution profile of the

15   anterior surface of the cornea. In addition, the method of the present invention allows a direct image of the eye to be generated without applying a substance to the corneal surface, which improves the accuracy of the measurement.

In a specific embodiment, the projected light is

20   reflected directly off the lateral surface of the patient's nose, or a reflector positioned between the eye and the lateral surface of the patients nose. The light is directed against this surface at an angle selected so that the light will reflect back across the front portion of the eye to "back

25   illuminate" the eye. This method overcomes the potential problem that the nose could interfere with the transmission of light obliquely across the eye. In addition, it allows the eye to be measured while minimizing the amount of light that passes directly into the eye, and without positioning the

30   optics directly in front of the eye. Preferably, a light pattern having a partially annular shape is projected against a diffuse reflector, such as baked enamel or white material attached to the patient's nose. This partially annular shape is similar to a crescent shape except that the ends of the

35   inventive shape do not taper to a point as in a crescent. The partially annular shaped light pattern reduces light scattering at the edge of the profile to increase the contrast and improve the resolution of the image.

The silhouette image will typically comprise a single meridian or plane of the eye, taken from a non-parallel angle relative to the optical axis of the eye (preferably perpendicular or substantially perpendicular to the optical

5   axis of the eye). To accurately image the entire outer profile of the cornea, a plurality of silhouette images of different meridians are generated, and then combined together to form a two or three dimensional image of the eye. These separate images may be created by moving the eye to different

10   positions, and imaging the eye at each position, or by moving the optics such that each image is generated from a different angle relative to the optical axis.

In another aspect of the invention, systems and methods are provided for generating a direct image of the

15   ablated corneal surface of the eye during or immediately following a surgical procedure, such as photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK), laser in-situ keratomileusis (LASIK) or the like. During the laser ablation procedure for PRK, the epithelium is removed to

20   expose the underlying Bowman's layer of the cornea. In LASIK procedures, the epithelium, Bowman's membrane and a portion of the anterior stroma are partially incised from the stroma and folded back to expose the stroma to the laser. An ultraviolet or infrared laser is employed to remove a microscopic layer of

25   anterior stromal tissue from the cornea to alter its refractive power.

According to another aspect of the present invention, one or more direct images are generated of the ablation profile of the cornea. The direct images are then

30   registered with one or more pre-ablation profiles of the cornea to characterize the profile of ablated corneas and to determine the spatial variance of tissue ablation rates during surgical procedures. This information is then used to generate a laser treatment based on the actual properties of

35   the eye to increase the precision of future laser ablation procedures. Alternatively, this information may be used in situ to alter the ablation algorithm during the procedure to compensate for spatial variations along the ablation profile.

In some embodiments, a number of ablation subtreatments are performed on the cornea, with each subtreatment having a shape and a depth selected so that the overall laser treatment ablates a desired shape and depth in the cornea. A direct image is generated of the ablation profile of each these subtreatments to calculate the laser treatment. In an exemplary embodiment, each subtreatment further comprises a plurality of laser pulses that combine to form the subtreatment. In this embodiment, a direct image is generated of the abated profile after each laser pulse so that the corneal profile of each laser pulse can be calculated to determine the overall laser treatment.

In one embodiment, direct images of a plurality of ablation profiles from different human eyes are generated, and a laser treatment is calculated based on an average ablation profile representing ablation characteristics of an average human eye. In another embodiment, the laser treatment for an individual eye is calculated based on one or more ablation profiles of that particular individual eye. The cornea is then subjected to another ablation treatment based on the newly calculated laser treatment for that particular eye. In yet another embodiment, the invention provides a method for generating a direct image of a plurality of ablation profiles with the same laser, and calculating the laser treatment based on ablation characteristics of that particular laser.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a simplified block diagram illustrating the functional relationships of generalized optical mechanical and electrical components of an optical system of the present invention;

Figs. 2 and 3 are flow charts illustrating the steps for calculating a laser treatment algorithm for ablating a desired shape onto the cornea according to the present invention;

Figs. 4 and 5 are front and isometric schematic views, respectively, of the optical system of Fig. 1,

illustrating a method of generating silhouette images of the
anterior region of the eye according to the present invention;

Fig. 6 is an enlarged view of a reflector of the
optical system of Fig. 1, illustrating a partial annular shape
5   that is projected onto the reflector in one embodiment of the
present invention;

Figs. 7 and 8 illustrate an image of the ablated
corneal surface of a human eye generated by an optical system
and method of the present invention;

10   Fig. 9 schematically illustrates a method for
generating images of the ablated corneal surface during a
laser ablation procedure; and

Fig. 10 illustrates a theoretical profile of
ablation depth versus position with (dashed line) and without
15   (solid line) a central island.

Fig. 11 illustrates an ablation similar to that of
Fig. 10 in which the ablation algorithm has been modified
using feedback from the corneal profiles of the present
invention.

20   Figs. 12A-16 illustrate alternative desired (dashed
lines) and actual (solid lines) ablation profiles which may
benefit from the present invention.

25   **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**
The present invention is directed to systems,
methods and apparatus for generating profiles of anterior
regions of the patient's eye, such as the anterior surface of
the cornea. The present invention is particularly useful for
30   imaging the anterior surface of the optically useful region of
the cornea. For convenience, the remaining disclosure will be
directed specifically to systems and methods for generating
profiles of the region of the cornea underlying the
epithelium, often referred to as Bowman's layer and/or the
35   anterior surface of the stroma (as well as the non-removed
portions of the epithelium). Bowman's layer and the stroma
are layers that can accommodate permanent change in the
contour of the cornea. However, it will be appreciated that

the system and method can be applied equally well to
procedures involving other tissue structures within the eye,
such as the epithelium or other regions of the cornea.

5   The present invention employs a light projecting
assembly to project light against a reflector such that the
reflected light passes across the anterior region of the eye,
and an image generating assembly to receive the light and
generate a direct, silhouette image of this anterior region.
The silhouette image created by the present invention will
10   typically comprise a two dimensional representation of the
outline or profile of the anterior region of the cornea. The
outline may be suitably processed such that the cornea is
depicted by a darker region outlined against a lighter
background to provide a sharp contrast at the edge of the
15   cornea. The silhouette image will typically comprise a single
meridian or plane of the eye, taken from a non-parallel angle
relative to the optical axis of the eye. Usually, the light
is reflected across the eye at an angle of about 70-110
degrees relative to the optical axis of the eye, and
20   preferably the light passes across the eye substantially
perpendicular to this axis. To accurately image the entire
outer profile of the cornea, a plurality of silhouette images
of different meridians are generated, and then combined
together to form a two or three dimensional profile of the
25   eye. These separate images may be created by allowing the
patient to move/rotate the eye into different known positions,
and imaging the eye at each position. These positions may be
established, for example, by having the patient sequentially
look at discrete light sources positioned at different angles
30   relative to the optical axis of the system. Alternatively,
the eye may be held in a fixed position and the optics may be
moved such that each image is generated from a different angle
relative to the optical axis.

Providing a direct, silhouette image of the front
35   edge of the cornea improves the resolution as compared to
previous methods that approximate the corneal profile based on
measuring reflected light patterns. For example, the
silhouette image generated by the present invention has

sufficient data points to minimize smoothing or approximation
of the curve at the anterior surface of the cornea, which
provides a high resolution profile of this surface. Usually,
the image will accurately portray surface contour changes on
5   the order of less than 20 microns, preferably less than 10
microns, and more preferably less than 3 microns.

In addition, the method of the present invention
allows a direct profile of the eye to be generating without
applying a substance to the corneal surface. By contrast,
10   rasterstereographic systems that project a grid on the cornea
which is then imaged by a video camera require the application
of talcum powder or a liquid film to the corneal surface in
order to visualize this surface. In these systems, the liquid
film or talcum powder is measured rather than the cornea.

15   The light is reflected in such a manner that it will
pass over the anterior region of the eye, preferably at an
angle that minimizes the amount of light scattering from the
corneal surface. In one embodiment, the light is reflected
directly off the lateral surface of the patient's nose, or a
20   reflector positioned between the eye and the lateral surface
of the patient's nose. In alternative embodiments, the light
is projected directly across the eye into a photodetector, or
into a mirror that reflects the light into a photodetector
remote from the eye. For example, this may be accomplished by
25   positioning a light source, aperture and projection lens to
project collimated light across the eye to infinity. The
light will pass across the anterior region of the eye at an
angle that will minimize the amount of light scattering from
the corneal surface and interfering with the generated image.
30   In addition, an aperture is preferably provided between the
reflector and the light detector to inhibit non-parallel light
from passing through the aperture to the detector. This
additionally minimizes or prevents light scattering from the
corneal surface that may interfere with the image.

35   The methods and apparatus of the present invention
are particularly useful for imaging the profile of the ablated
region of the cornea during or immediately following a laser
ablation procedure, such as photorefractive keratometry (PRK),

phototherapeutic keratectomy (PTK), laser *in situ*
keratomileusis (LASIK) or the like. These methods and
apparatus allow the surgeon to precisely image the exterior
edge of the eye to characterize the profile of ablated corneas

5   and to determine the spatial variance of tissue ablation rates
during the surgical procedures. Accordingly, the silhouette
images are preferably generated immediately following the
ablation of the cornea before the cornea heals, and before the
epithelium regrows (i.e., PRK and PTK procedures), or before

10   it is reattached to the cornea (LASIK procedures). These
images may be created after the ablation procedure has been
completed, or they may be created during the procedure, e.g.,
between laser pulses to capture the ablation profile of each
pulse. In the former case, the profiles may be used to

15   provide feedback regarding the ablation properties of the eye.
This feedback may then be used to further tailor or modify the
ablation algorithm, and to program the modified ablation
algorithm into the laser system prior to subsequent
treatments. In the latter case, this feedback may be used *in*

20   *situ* to alter the ablation algorithm during the surgical
procedure.

        Referring to Fig. 1, an optical system 2 for
generating images of anterior portions of the eye is
schematically illustrated according to the present invention.

25   Optical system 2 includes a light source 4 for directing a
single or a plurality of light rays 6 through an aperture 9
and a projection lens 8 onto a reflector 10. The light rays 6
are reflected from reflector 10 across the exterior surface of
the cornea 12 into an imaging lens 14. Imaging lens 14

30   focuses the reflected light 16 through an aperture 18 and onto
a photodetector 20 to form the measurable optical images. A
signal switch 22, a frame grabber 24, and a computer 26 are in
electrical communication with the photodetector 20 for
digitizing the video images and processing these images with,

35   e.g. an edge detection program, for determining the corneal
profile.

        The light source 4 is activated by a power supply 28
to pass light rays 6 through aperture 9 and projection lens 8

and aperture 9, which preferably images aperture 9 onto
reflector 10.   The light source 4 may comprise one or more
light sources, e.g., lasers such as argon, helium-neon, diode,
dye, or other light sources, such as halogen light sources,
5   light emitting diodes, fiberoptics, and the like.   In one
embodiment, the light source will emit light having a red to
near infrared wavelength, about 700-900 nanometers. This
wavelength range has the highest sensitivity for many
detectors, and it also allows the optics to filter light from
10   other sources, such as an ultraviolet or infrared laser, a
microscope viewing light or the light from the operating room
(which is typically in the 400 to 700 nanometer range). The
light source may be configured to directly emit such
wavelengths, e.g., filtered halogen light sources that only
15   transmit wavelengths within the red to near infrared range.
        Projection lens 8 is preferably constructed such
that it will image the aperture 9 onto reflector 10.   As
discussed below, lens 8 will typically be positioned to the
side of the patient's head, and reflector 10 will typically be
20   positioned between the cornea and the patient's nose (see
Figs. 4 and 5).   Therefore, the focal length of lens 8 will
depend on the preferred position of the optics relative to the
patient.   Aperture 9 comprises an opening having a partially
annular shape that is approximately the same shape as the
25   anterior surface of the cornea (see Fig. 6).   The partially
annular shape of the opening will preferably be similar to a
crescent shape without the tapered points at either end.   The
opening will be shaped to allow a partially annular shaped
light pattern therethrough having a width sufficient to
30   illuminate the exterior portion of the eye.   Usually, the
projected aperture will have a width of about 6 to 12 mm, and
preferably about 8 to 10 mm.   The partially annular shaped
light pattern improves the resolution of the line or curve
between the dark and light regions of the image.   Since the
35   eye appears as a dark object with a light background, light
which scatters from the surface of the eye and is imaged onto
the detector can make the upper edge of the eye appear light
rather than dark.   Illuminating the eye from behind can

minimize this decreased contrast. This illumination minimizes
the amount of light which strikes the front surface of the eye
as seen by the detector, thereby increasing image contrast and
profile resolution. The above illumination can be
5   accomplished by projecting collimated light over the eye, or
by projecting a partial annulus sufficiently far behind the
eye such that the light rays passing over the eye and into the
imaging lens are nearly collimated. Because of this
illumination, relatively few light rays will illuminate the
10   front surface of the portion of the eye seen by the detector.
An annulus is a preferred geometry to project onto a diffusing
surface behind the eye because it will minimize the amount of
scattered light striking the front surface of the eye as seen
by the detector.
15   The reflector 10 may comprise any diffuse surface
that minimizes non-uniform light scattering, such as white
tape attached to the patient's nose, baked enamel attached to
a speculum behind the eye or the like. Of course, light may
be reflected directly off the patient's nose. Since the nose
20   is not a uniformly scattering surface, however, a reflector 10
having a uniformly scattering surface is preferable. The
reflector 10 is positioned relative to the light source 4 and
the projection lens 8 such that scattered light is occluded by
the front surface of the eye prior to imaging lens 14. This
25   projection system overcomes the potential problem that the
nose could interfere with the transmission of light across the
eye. In addition, it allows the eye to be measured while
minimizing the amount of light that passes directly into the
eye, and without requiring that the optics be positioned
30   directly in front of the eye.
              In an alternative embodiment, reflector 10 may
comprise a mirror (not shown) that is suitably designed and
positioned to reflect light obliquely across the eye to
photodetector 20. In this embodiment, projection lens 8 is
35   configured to project collimated light into the mirror and
across the eye. The mirror serves to reflect collimated light
across the eye and onto photodetector. In yet another
alternative, light source 4, aperture 9 and lens 8 may be

positioned to project light directly over the eye. In this
embodiment, the light source may comprise one or more light
emitting diodes (e.g., arranged in a crescent or partially
annular array) that project light across the eye into the
5   photodetector, which processes the light signals to generate
the image.

The reflected light rays 16 pass through imaging
lens 14, which focuses the rays through an aperture 18 and
forms an image of the eye on the photosensitive surface of the
10   photodetector 20. In an exemplary embodiment, imaging lens 14
is configured to minimize distortion and aberration across the
image. Further, imaging lens 14 may comprise a telecentric
lens to maintain constant magnification with increased depth
of field. In preferred aspects, the invention may further
15   employ autofocus systems to focus both the projected light 6
onto reflector 10 and the reflected light 16 onto
photodetector 20.

Aperture 18 will usually have a diameter of about 1
mm, and is preferably positioned at the focal length of the
20   imaging lens 14 to provide improved depth of field and to
remove spurious light which will degrade the contrast at the
edge of the eye. Aperture 18 effectively ensures that only
light travelling parallel or near parallel to the optic axis
of lens 14 will pass through aperture 18. In addition,
25   filters such as dichroic mirrors or beam splitters may be
included in the optical train to filter spurious light. These
filters are transmissive to radiation at the wavelength of the
light source while reflective to radiation at other
wavelengths thus effectively separating the light rays 6
30   projected onto reflector 10 from other light sources in the
operation room.

Electrical output signals generated by photodetector
20 are directed by signal switch 22 to a frame grabber 24
which produces a time sequence series of electrical signals
35   representative of the spatial distribution of energy and the
image formed by lens 14. These electrical signals can be
displayed as a real-time video image in a display apparatus
30. Alternatively or in addition, the electrical signals can

be stored in digital form by a frame grabber 24 for further
analysis by a computer 26 and/or for supply to display
apparatus 30. Computer 26 will include a processor and
appropriate software, such as an edge detection program for
determining the edge of the eye to increase the resolution of
the corneal profile. Special algorithms may also be stored in
computer 26 for computation of the corneal profile,
registration of the ablated profile with a pre-ablated profile
of the cornea, etc. Some of these algorithms are discussed in
more detail below.

Photodetector 20 may comprise a conventional
photodetecting device having photocathodes and a video contact
image. Alternatively, photodetector 20 may comprise an array
of discrete detectors such as a charge coupled device (CCD).
Typically, the detector would comprise a CCD array with usable
aperture dimensions of about 6.6 by 8.7 mm and would be
sensitive to the light emitted by light source 4. Selecting
an appropriate number of resolution elements for the detector
array can vary the resolution of the system. For example, to
obtain a desired resolution of 3 μm, the imaging system would
be configured so as to provide at least 1 pixel per 6μm of
elevation on the eye. By interpolating between pixel
elements, resolution of 3μm may be obtained. Many suitable
detectors are commercially available such as the Electrim EDC
1000U (Electrim Corporation, Princeton, N.J.) which provides
an array of 972 by 1134 detector elements. With this camera,
a 5.8 mm portion of an eye imaged to 6.6 mm at the detector
will provide one pixel for each 6 μm of elevation of an eye.
If desired, detectors with a substantially greater number of
elements may be utilized.

Referring to Fig. 2, a method for calculating a
laser treatment algorithm for ablating a desired shape onto
the cornea will now be described. The physician conducts an
initial patient evaluation 200 to determine whether the
patient's cornea is suitable for a laser ablation procedure
and to determine the refractive error that will be corrected,
e.g., myopia, hyperopia, hyperopic astigmatism, myopic
astigmatism, mixed astigmatism or the like. After this

evaluation is completed, patient parameter information 202
will be collected. For example, the nature and size of the
refractive error will be determined to calculate the desired
ablation shape that will be applied to the patient's cornea.
5   This information may be obtained from the patient's eyeglass
or contact prescription, or a measurement of the curvature and
refractive power of the patient's cornea through corneal
topographic analysis (e.g., keratometry, photokeratoscopy
and/or videokeratography). The information regarding patient
10   parameters is then used to prepare one or more ablation
algorithm(s) or a laser treatment 204 for ablating a desired
corrective shape onto the cornea.

        In addition to patient parameter information 202,
experimental ablation data 206 may also be used in the
15   calculation of the laser treatment algorithms(s) 204. This
experimental ablation data 206 includes, among other things,
the spatial and temporal distribution of laser pulses required
to ablate the desired corrective shape onto the cornea. The
ablation algorithm may also be modified based on post-
20   operative clinical ablation data 208. The clinical data 208
is typically obtained during a follow up examination 218 of
the patient after a laser ablation procedure has been
completed. This clinical data 208 may, for example, include
differences between the theoretical and measured ablation
25   profiles, such as central islands.

        In addition, a treatment program 210 for ablating
the desired shape onto the cornea based on the above factors
will be determined for the particular operation. Fig. 3 is a
flow diagram of an exemplary treatment program 210, but it
30   will be recognized that a variety of other treatment programs
may be employed. As shown, the laser treatment for the
particular patient is evaluated 240 and divided into a series
of subtreatments 242. For example, if a -6D ablation is
desired, the laser may be programmed to ablate a series of -1D
35   ablations. These subtreatments are then further broken down
into a series of discrete laser pulses 244 in which the laser
is configured to a desired state prior to each pulse. To
produce the desired shape on the cornea, the subtreatments 242

may then be individually modified 246, or the summation of
subtreatments 248 may be designed to produce the desired
shape. Finally, desired treatment is displayed on a video
display 250 or similar display apparatus.

5   Referring again to Fig. 2, after the laser treatment
has been calculated, a preprogrammed shape is ablated onto the
patient's cornea at step 220. During or immediately following
this ablation, the ablated corneal profile is directly
measured at step 222 as discussed below in reference to Figs.

10 4 and 5. This measurement will provide a corneal ablation
profile that allows measurement of the spatial variation of
tissue ablation with laser irradiance for an actual eye. This
measurement is then used as feedback 224 to modify the
ablation algorithm for the laser treatment in future

15 procedures. Typically, measurements will be conducted for a
number of different procedures and then normalized to
determine an ablation profile for the "average" eye. This
normalized ablation profile is used to provide a more accurate
laser treatment program. Alternatively, the feedback 224 may

20 be employed *in situ* to modify the ablation algorithm, modulate
the laser beam, etc., such that the actual ablation profile
closely approximates the desired profile.

        The measurements of the corneal ablation profile may
be taken after the entire treatment has been conducted,

25 between subtreatments and/or between each discrete laser
pulse. In the latter cases, a number of laser treatments may
be custom generated based on the ablation profiles of each
subtreatment and/or laser pulse in the procedures. For
example, if a -10D ablation is desired, the laser may be

30 programmed to ablate a series of -1D ablations or
subtreatments, with a measurement taken between each -1D
ablation. Each measurement is then registered with the pre-
ablation profile to determine an actual shape and depth of
each subtreatment.

35   The laser treatment is calculated by generating a
pre-ablation profile of the cornea, storing this pre-ablation
profile in a memory and registering the ablated profile with
the pre-ablation profile to determine a spatial variation of

tissue ablation on said region of the cornea. In a preferred
embodiment, the pre-ablation profile is larger than the
selected ablation region so that it include portions of the
cornea that are peripheral to the ablated region. The direct
5   image also includes these peripheral regions so that the pre
and post ablation profiles can be registered by aligning the
peripheral regions of the direct image with the peripheral
regions of the pre-ablation profile.

Referring to Figs. 4 and 5, an exemplary optical
10   system 50 is illustrated and described in use for generating
images of the anterior region of a patient's eye E. As shown,
optical system 50 is preferably disposed toward the side of
the patient's head to project light across the patient's eye
to minimize scattered light, which could interfere with the
15   image. In addition, this configuration minimizes interference
with the laser apparatus and/or surgical microscope that will
be used during a surgical procedure (see Fig. 9). Projecting
light from the side of the patient's head in this manner and
generating images without measuring the reflected light from
20   the eye allows the images to be generated intraoperatively.
Thus, for example, direct silhouette images may be generated
during or immediately following a laser ablation procedure so
that a profile of the actual ablated surface of the Bowman's
layer or the stroma can be obtained (i.e., without the tear
25   film or the regrown epithelium layer).

The optical system 50 may include a suitable patient
station (not shown) of known design used to position the
patient's eye at a desired position in three dimensional
space. The eye is positioned so that the anterior portion is
30   in focus and centered on the image detector. The imaging
system is aligned with the laser so that the eye is positioned
properly for both laser treatment and profilometry. This
alignment permits measurements of the eye during surgery
without requiring that the treatment be interrupted to align
35   the eye with the profilometer.

As shown in Figs. 4 and 5, light from light source 4
is projected through aperture 9 and lens 8 such that it
strikes reflector 10 on the patient's nose. Preferably, the

light will strike at an acute angle relative to the horizontal
eye axis A at a point behind the eye such that the reflected
light 16 passes across the eye generally parallel to axis A.
Since the distance between the lateral surface of the nose and
5   the cornea will vary for different individuals, light source
4, aperture 9 and lens 8 will be vertically movable relative
to reflector 10. Preferably, the angle between the projected
light 6 and the reflected light 16 will be substantially
constant (usually about 1 to 10°) regardless of this distance.
10   Accordingly, light source 4, aperture 9 and/or lens 8 will be
adjusted vertically relative to horizontal axis A such that
the aperture 9 imaged onto reflector 10 is reflected directly
across the target region of the cornea. Light source 4 may be
moved manually, or with suitable drive motors that may be
15   controlled by computer 26.

        The reflected light 16 passes over the anterior
region of the cornea to imaging lens 14, where a portion of
the light 16 is occluded by the cornea, as discussed above.
The parallel light is then focused through aperture 18 and
20   imaged onto photodetector 20. Reflected light rays which are
not substantially collimated are occluded by aperture 18. The
image is processed with frame grabber 24 and computer 26. The
projected light 6 will preferably have a partially annular
shape that substantially corresponds with the outer contour of
25   the cornea, and having a width sufficient to create a two-
dimensional silhouette image that extends on either side of
the exterior surface of the cornea. This typically creates a
high contrast image of a single meridian of the cornea. The
high contrast image includes a line or curve that represents
30   the outer edge or profile of the cornea. Usually, this line
will accurately portray surface contour changes on the order
of less than 20 microns, preferably less than 10 microns, and
more preferably less than 3 microns.

        By ensuring that the eye is properly aligned, the
35   generated image allows the precise measurement of the distance
between a reference point and the exterior surface of the
cornea. Thus, by registering this image with, e.g, a pre-
ablation profile of the cornea, the ablation profile may be

calculated. To that end, the light rays 6 projected onto reflector 10 will typically be sized so that they pass over the entire ablation region, and onto a portion of the non-ablated region of the cornea (either above and below the

5   ablated region, or on either side of this region). The profile of the non-ablated region of the cornea can be used to register the post-ablation profile with the pre-ablation profile. An example of a silhouette image of a human eye which might be generated according to the systems and methods

10   of the present invention is illustrated in Figs. 7 and 8.

Referring to Fig. 9, a method for generating a direct, silhouette image of the anterior surface of the cornea during or immediately following a surgical procedure will now be described. The present invention may be used in

15   conjunction with a wide variety of surgical procedures on the eye, and is particularly useful with laser ablation procedures, such as photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK), laser in-situ keratomileusis (LASIK) or the like. In such procedures, a

20   laser is prepared to deliver the appropriate radiation in accordance with the calculated beam delivery parameters for the specific procedure, e.g., the power level and spatial location on the corneal surface. In PRK or PTK procedures, the epithelium is completely removed to expose the anterior

25   region of the stroma. In LASIK procedures, the epithelium, Bowman's membrane and a portion of the anterior stroma are partially incised from the stroma and folded back to expose the stroma to the laser. The laser beam is typically controlled to impinge upon an area of the cornea of an eye to

30   form therein a predetermined ablation shape. The laser selected for use preferably emits in the ultraviolet, namely at wavelengths of less than substantially 400.0 nm.

For convenience, the method will be described as applied to a laser photo ablation method (PRK) using an argon

35   fluoride excimer laser which generates ultraviolet radiation at 193.0 nm at predetermined pulse energy densities and repetition rates. In an exemplary embodiment, a VISX STAR Excimer Laser System™ may be used for the ablation

(commercially available from VISX, Incorporated, of Santa
Clara, California). This system produces an output of 193.0
nm, operates at a frequency of 6.0 Hz and is adjusted to
deliver uniform fluency of 160.0 millijoules/cm^2 with a 6.0 mm
5   diameter ablation zone. Other laser systems suitable for use
with the present invention are the T-PRK^R scanning and
tracking laser from Autonomous Technologies Corporation, the
SVS Apex laser from Summit Technology Inc., the Keracor™ 117
scanning laser system from Chiron Vision, or the like.
10   As shown in Fig. 9, a representative photoablation
laser surgery apparatus and system 100 using the laser
delivery system 102 and an associate power supply control
system (not shown) pilots a laser beam 106 onto a cornea of an
eye E. A microscope 116 with a viewing path coinciding with
15   the laser beam may be used to align the laser beam with the
optical axis of the eye, and for observing the laser ablation
procedure. An aspirator (not shown) may be positioned above
the ablation region to capture the plume as it lifts from the
surface. PRK ablation algorithms are typically used to
20   control the spatial and temporal distribution of the laser
pulses. Suitable algorithms for use with the present
invention are discussed in Munnerlyn, C.R., et al.
*Photorefractive Keratectomy: A Technique For Laser Refractive
Surgery*. J. Cataract Refract. Surg. (1988) 14:46-52. Other
25   ancillary components of the laser surgery system 100 which are
not necessary to an understanding of the invention have been
omitted to avoid prolixity. Further details of suitable
system and methods for performing a laser ablation procedure
can be found in commonly assigned U.S. Patent Nos. 4,665,913,
30   4,669,466, 4,732,148, 4,770,172, 4,773,414, 5,207,668,
5,108,388, 5,219,343 and 5,163,934, the complete disclosures
of which are hereby incorporated herein by reference.
                During or immediately following the laser ablation
procedure, optical system 50 may be used to generate
35   silhouette images of the ablated portions of the cornea. It
will be appreciated that, for a number of reasons discussed
above, the present invention allows these images to be
generated without substantially interfering with the laser

ablation process, or the surgeon's view of the site. To
determine the ablation profile, a pre-ablation image is
generated before radiation is delivered to the cornea to
establish one or more reference images. These reference

5   images are then registered with the post-ablation images to
measure the shape of ablation across the cornea. Because
slight amounts of eye motion can produce errors in the
measured ablation, the corneal profiles are aligned using
unablated portions of each profile prior to registration of

10   the profiles.

As discussed above, each image will generally
illustrate a single meridian of the cornea corresponding to
the highest elevation of the cornea. However, in cases where
the eye is irregular the highest elevation of the cornea

15   measured may deviate from the intended meridian. Accordingly,
a number of images may be taken of different meridians to
generate a two or three dimensional image of the cornea. One
method of accomplishing this is to provide an array of point
light sources 150, such as LED's, in front of the eye. The

20   point light sources 150 are illuminated sequentially. As the
patient looks at each point light source 152 within the array
150, an image of the cornea will be generated. Alternatively,
an eye tracking system may be used that automatically keeps
track of the eye's position during the imaging processing.

25   The eye tracking system will feed this information to the
computer so that the position of the eye can be determined for
each image. Suitable eye tracking systems are commercially
available.

The images may be generated after the ablation

30   procedure has been completed to determine the shape of tissue
ablation rates and to evaluate the feasibility of changing the
distribution of laser pulses during PRK. Alternatively, the
images may be generated between laser pulses to determine the
ablation geometry as the laser treatment proceeds. With this

35   method, the information may be processed and fed into the
ablation algorithm to provide feedback to modify the ablation
algorithm. This information may be used immediately to
improve the present procedure *in situ*, or it may be analyzed

and used to modify the ablation algorithm for future treatments. For example, if the images indicate that a central island is being formed with the laser pulses, the computer may change the ablation algorithm to ablate more tissue in the central area of the cornea, as can be understood with reference to Figs. 10-16. This iterative process allows the surgeon to generate the appropriate depth of ablation of the specific procedure *in situ* or for later treatments.

Alternatively, if the amount of tissue removal is greater than anticipated, the programmed laser treatment may be decreased to avoid over correction. For example, if a -10D ablation is desired, the laser may be programmed to ablate a series of -1D ablations, with a measurement taken between each -1D ablation. After 9 -1D ablations, the profilometer may show -9.5D of ablation. Consequently, the laser is programmed to ablate -0.5D on the 10th ablation to achieve an improved result.

The present invention may be used to determine the ablation characteristics of the "average" human eye by compiling information from the images generated from a number of different eyes. Alternatively, the inventors have recognized that there are individual differences in the ablation characteristics of each person's eyes. Accordingly, the present invention may be used to determine the ablation characteristics of an individual eye so that the ablation algorithm may be customized for each individual eye. In yet another embodiment, a plurality of ablation profiles taken with the same laser may be compiled to calculate a laser treatment based on the ablation characteristics of that individual laser.

In addition, it should be noted that although the present invention has generally been described in use with a stationary laser system, it should be clearly understood that the invention is not limited to this type of system. For example, the systems and methods described herein may be employed in conjunction with a scanning laser system, such as the T-PRK[R] scanning and tracking laser from Autonomous Technologies Corporation or the Keracor™ 117 scanning laser

system from Chiron Vision. With scanning laser systems, the
images may be generated after the procedure is completed, or
during the procedure. In the latter case, for example, images
may be generated of the already scanned portions of the
5   cornea, while the laser is completing ablation of the
remaining portions of the cornea. The known laser
characteristics of an individual laser may also be used to
correct other laser of a similar configuration, particularly
those of the same make and model.

WHAT IS CLAIMED IS:

1   1.   A method for generating a laser treatment for
2   ablating a desired shape onto a patient's cornea, the method
3   comprising:
4   selectively ablating and shaping a region within the
5   cornea;
6   generating a direct profile of the ablated region;
7   and
8   calculating a laser treatment for ablating a desired
9   shape onto the patient's cornea based on the ablated profile
10 of the region.

1   2.   The method of claim 1 further comprising:
2   generating a pre-ablation profile of said region of
3   the cornea prior to the selectively ablating step;
4   storing the pre-ablation profile in a memory; and
5   registering the ablated profile with the pre-
6   ablation profile to determine a spatial variation of tissue
7   ablation on said region of the cornea.

1   3.   The method of claim 2 further comprising
2   calculating the laser treatment based on said spatial
3   variation of tissue ablation.

1   4.   The method of claim 1 wherein the generating
2   step comprises:
3   projecting light against a surface adjacent to or
4   near the eye;
5   reflecting the light from the surface across an
6   anterior region of the eye; and
7   receiving the projected light to generate a direct
8   image of the ablated profile of the eye.

1   5.   The method of claim 1 further comprising:
2   generating a pre-ablation profile of a non-ablated
3   region of the cornea, wherein said non-ablated region includes
4   portions peripheral to the ablated region of the cornea and

5   wherein the direct profile includes said peripheral portions;
6   and
7   registering the pre-ablation profile with the
8   ablated profile by aligning the peripheral portions of the
9   direct profile with the pre-ablation profile.

1   6.   The method of claim 1 further comprising
2   generating a plurality of ablation profiles from different
3   human eyes, and calculating the laser treatment based on an
4   average ablation profile representing ablation characteristics
5   of an average human eye.

1   7.   The method of claim 1 further comprising
2   calculating the laser treatment for an individual eye based on
3   one or more ablation profiles of said individual eye, and
4   selectively ablating and shaping said region of said cornea
5   after the calculating step.

1   8.   The method of claim 1 further comprising
2   generating a direct profile of a plurality of ablation
3   profiles with the same laser, and calculating the laser
4   treatment based on ablation characteristics of said laser.

1   9.   The method of claim 1 wherein the selectively
2   ablating and shaping step comprises performing a number of
3   ablation subtreatments on said region each having a sub-depth
4   and a sub-shape, the method further comprising generating a
5   direct profile of said region between each subtreatment, and
6   calculating a sub-laser treatment for each ablation
7   subtreatment.

1   10.   The method of claim 9 wherein each subtreatment
2   further comprises a plurality of laser pulses designed to
3   ablate the region at the sub-depth and the sub-shape for the
4   particular laser pulse, the method further comprising
5   generating a direct profile of said region between laser
6   pulses, and calculating the sub-laser treatment based on the
7   ablation profile following a laser pulse.

1   11.   The method of claim 1 further comprising
2   calculating the laser treatment based on post operative
3   clinical data.

1   12.   The method of claim 1 further comprising
2   calculating the laser treatment based on experimental ablation
3   data.

1   13.   The method of claim 1 further comprising
2   calculating the laser treatment based on individual patient
3   parameters.

1   14.   A method for generating a profile of an
2   anterior region of a patient's eye comprising:
3   projecting light against a surface adjacent to or
4   near the eye;
5   reflecting the light from the surface across an
6   anterior region of the eye; and
7   receiving the projected light to generate a direct
8   profile of the anterior region of the eye.

1   15.   The method of claim 14 wherein the epithelium,
2   Bowman's layer and a portion of the anterior stroma have been
3   removed or ablated to expose a surface region of the stroma,
4   the method further comprising generating a direct profile of
5   said surface region.

1   16.   The method of claim 14 wherein the direct
2   profile is generated of a corneal surface that is directly
3   exposed to the ambient environment without applying a
4   substance to said corneal surface.

1   17.   The method of claim 14 further comprising:
2   imaging light onto a photodetector; and
3   processing signals from the photodetector to
4   generate a two dimensional silhouette image of at least a
5   portion of an anterior surface of the cornea.

1   18.   The method of claim 14 wherein a first portion
2   of the reflected light is occluded by the cornea and a second
3   portion of the reflected light passes across the eye and is
4   received by a photodetector, the method further comprising
5   generating a silhouette image having a dark portion
6   representing the first portion of the reflected light and a
7   light portion representing the second portion of the reflected
8   light.

1   19.   The method of claim 18 wherein the dark and
2   light portions of the image form a line therebetween
3   representing a profile of the cornea.

1   20.   The method of claim 14 wherein the direct
2   profile comprises a corneal profile that depicts surface
3   changes of less than 20.0 μm.

1   21.   The method of claim 14 further comprising
2   focusing the reflected light onto an aperture to increase a
3   depth of field of the image.

1   22.   The method of claim 14 wherein the profile
2   comprises a single meridian of the cornea.

1   23.   The method of claim 14 wherein the surface is a
2   reflector having a uniformly scattering surface and located
3   between the eye and the lateral surface of the patient's nose.

1   24.   The method of claim 14 wherein the projecting
2   step is carried out by projecting a partially annular shaped
3   light pattern onto the surface.

1   25.   The method of claim 14 wherein the first
2   profile is generated at a first position of the eye, the
3   method further comprising:
4   moving the eye from the first position to a second
5   position;
6   projecting light onto said surface;

7   reflecting the light off the surface across the
8   anterior region of the eye; and
9   receiving the reflected light to generate a second
10   profile of the anterior region of the eye in the second
11   position.

1   26.   The method of claim 25, wherein the first and
2   second profiles each comprise a different meridian.

1   27.   The method of claim 14 wherein the light has a
2   wavelength of about 700 to 900 nanometers.

1   28.   The method of claim 14 further comprising
2   ablating a tissue structure within the cornea, and generating
3   a direct profile of a corneal surface underlying the ablated
4   tissue structure immediately following the ablating step.

1   29.   The method of claim 14 further comprising
2   calculating a laser treatment for ablating a desired shape
3   onto the patient's cornea based on the direct profile of the
4   anterior region of the eye.

1   30.   A method for performing a surgical procedure on
2   a human eye comprising:
3   ablating a tissue structure within the cornea; and
4   during or immediately following the ablating step,
5   generating a direct profile of an exposed corneal surface.

1   31.   The method of claim 30 further comprising
2   exposing an anterior surface of the cornea to the ambient
3   environment and generating a direct profile of the anterior
4   surface without applying a substance to the anterior surface.

1   32.   The method of claim 30 wherein the ablating
2   step comprises projecting ultraviolet radiation onto the
3   cornea to ablate a tissue structure on the optically useful
4   portion of the anterior surface of the cornea.

1   33.   The method of claim 30 wherein the cornea
2   comprises an epithelium, a Bowman's layer and a stroma, the
3   method further comprising removing the epithelium and at least
4   a portion of the Bowman's layer from the anterior region of
5   the cornea to expose a selected region of the Bowman's layer
6   and/or the stroma and ablating a portion of the Bowman's layer
7   and/or the stroma within the selected region.

1   34.   The method of claim 33 further comprising
2   generating a direct profile of the ablated portion of the
3   Bowman's layer and/or stroma after the epithelium has been
4   removed and prior to regrowth of a new epithelium layer.

1   35.   The method of claim 30 wherein the direct
2   profile is generated before the cornea has healed.

1   36.   The method of claim 30 wherein the direct
2   profile is generated less than about 48 hours after the
3   ablating step has been completed.

1   37.   The method of claim 30 wherein the direct
2   profile is generated less than about 4 hours after the
3   ablating step has been completed.

1   38.   The method of claim 30 wherein the generating
2   step comprises projecting light across an anterior region of
3   the eye to create a silhouette image of said anterior region,
4   wherein a first portion of the reflected light is occluded by
5   the cornea and a second portion of the reflected light passes
6   across the eye and is received by a photodetector, the method
7   further comprising generating a silhouette image having a dark
8   portion representing the first portion of the reflected light
9   and a light portion representing the second portion of the
10   reflected light.

1   39.   The method of claim 38 wherein the dark and
2   light portions of the image form a line therebetween

3 representing a profile of the cornea, the profile depicting
4 surface changes of less than 20.0 μm.

1   40. The method of claim 30 further comprising:
2   projecting light against a surface adjacent or near
3 the eye;
4   reflecting the light off the surface across an
5 anterior region of the; and
6   receiving the reflected light to generate a
7 silhouette image of the anterior region of the eye.

1   41. The method of claim 32 further comprising
2 generating a reference profile of the anterior surface of the
3 selected region of the cornea prior to the ablating step, and
4 registering the ablated profile with the reference profile to
5 determine a depth of tissue ablation achieved during the
6 ablating step.

1   42. An optical system comprising:
2   a reflector configured for positioning adjacent to
3 or near the eye;
4   a light source projecting light onto the reflector
5 such that at least a portion of the light is reflected across
6 an anterior region of the eye; and
7   an image generating system for receiving the
8 reflected light and generating a direct profile of the
9 anterior region of the eye.

1   43. The optical system of claim 42 wherein the
2 image generating system comprises a photodetector and a lens
3 positioned to receive the reflected light from the reflector
4 and to image the reflected light onto the photodetector.

1   44. The optical system of claim 43 wherein the
2 image generating system further comprises means for processing
3 signals from the photodetector and for generating a profile of
4 the anterior region of the eye that corresponds to said
5 signals.

1   45.   The optical system of claim 42 further
2   comprising an aperture positioned along the optical path
3   between the light source and the reflector, the aperture
4   having a partially annular shaped opening for projecting a
5   partially annular shaped light pattern onto the reflector.

1   46.   The optical system of claim 42 wherein the
2   light source emits light having a wavelength of between about
3   700 to 900 nanometers.

1   47.   The optical system of claim 42 further
2   comprising an aperture positioned between a lens and a
3   photodetector, the lens focusing the projected light onto the
4   aperture to increase a depth of field of the image.

1   48.   The optical system of claim 42 wherein the
2   reflector has a uniformly scattering surface positioned
3   between the patient's eye and the lateral surface of the
4   patient's nose.

1   49.   The optical system of claim 42 wherein the
2   image includes a dark region representing the cornea and a
3   light region, the generating system further comprising a
4   processor having edge detection software for determining a
5   line between the dark and light regions representing the
6   profile of the cornea, wherein the line depicts surface
7   elevation changes of less than 20.0 μm.

1   50.   The optical system of claim 42 further
2   comprising an eye positioning assembly for determining a
3   position and orientation of a selected region of the eye.

1   51.   The optical system of claim 50 wherein the eye
2   positioning assembly comprises an array of point light sources
3   located at predetermined positions with respect to the eye.

1   52. An optical system comprising:
2   a laser assembly for projecting radiation onto a
3 selected region of an anterior surface of a cornea to effect
4 ablation of said selected region to a certain depth;
5   a light projecting assembly for projecting light
6 across the anterior surface of the selected region; and
7   an image generating assembly for generating a direct
8 profile of the selected region of the cornea during or
9 immediately following ablation of said selected region.

1   53. The optical system of claim 52 wherein the
2 direct profile is generated with the surface region directly
3 exposed to the ambient environment and without applying a
4 substance to the surface region.

1   54. The optical system of claim 52 further
2 comprising a processing assembly, a memory for storing a pre-
3 ablation profile of the selected region, and means for
4 registering the ablation profile with the pre-ablation profile
5 to determine an actual depth of tissue ablation within the
6 selected region.

1   55. The optical system of claim 54 wherein the
2 processing assembly includes means for comparing the ablation
3 profile with a reference ablation profile and means for
4 calculating a laser ablation algorithm based on differences
5 between the ablation profile and the reference ablation
6 profile.
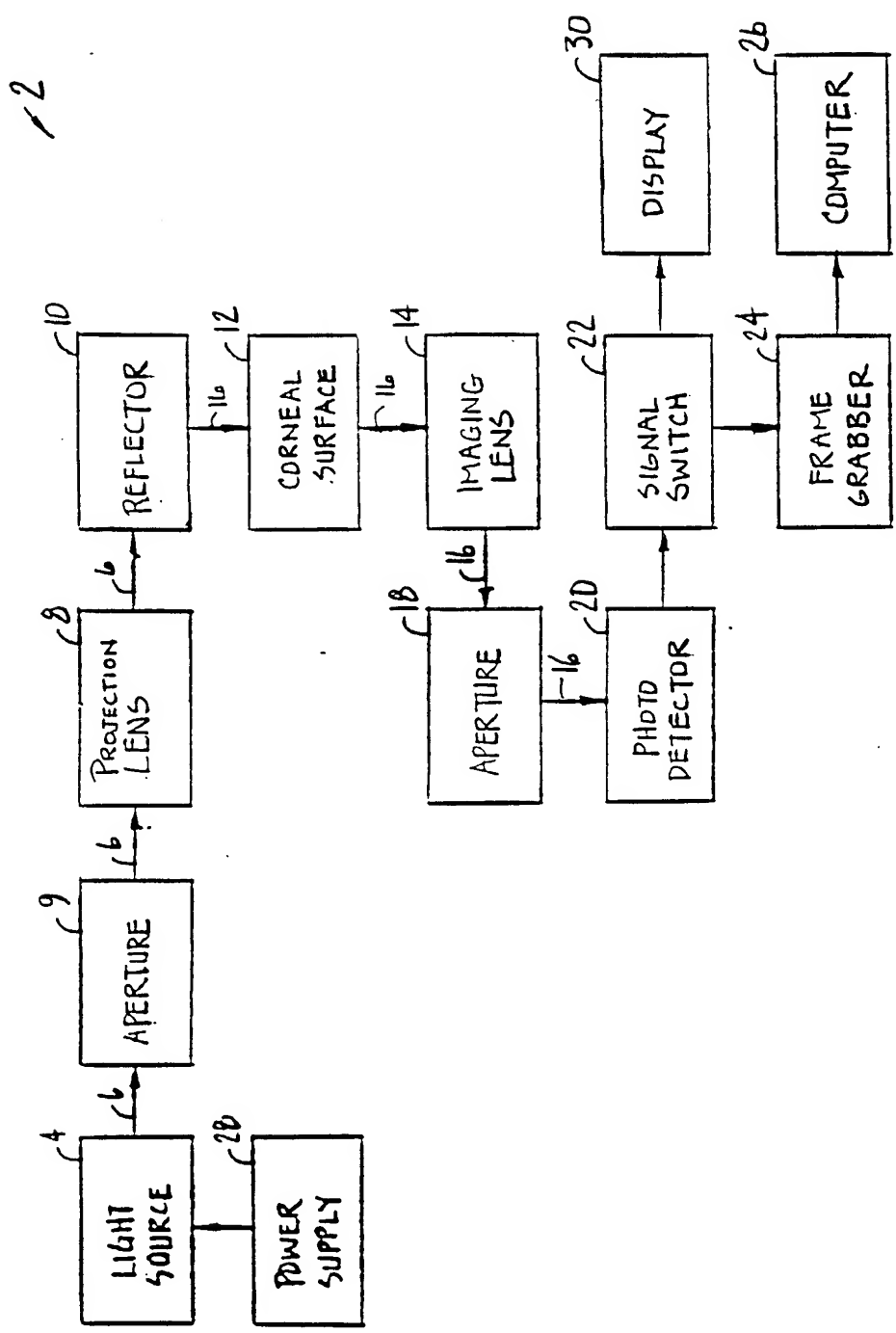
FIG. 1
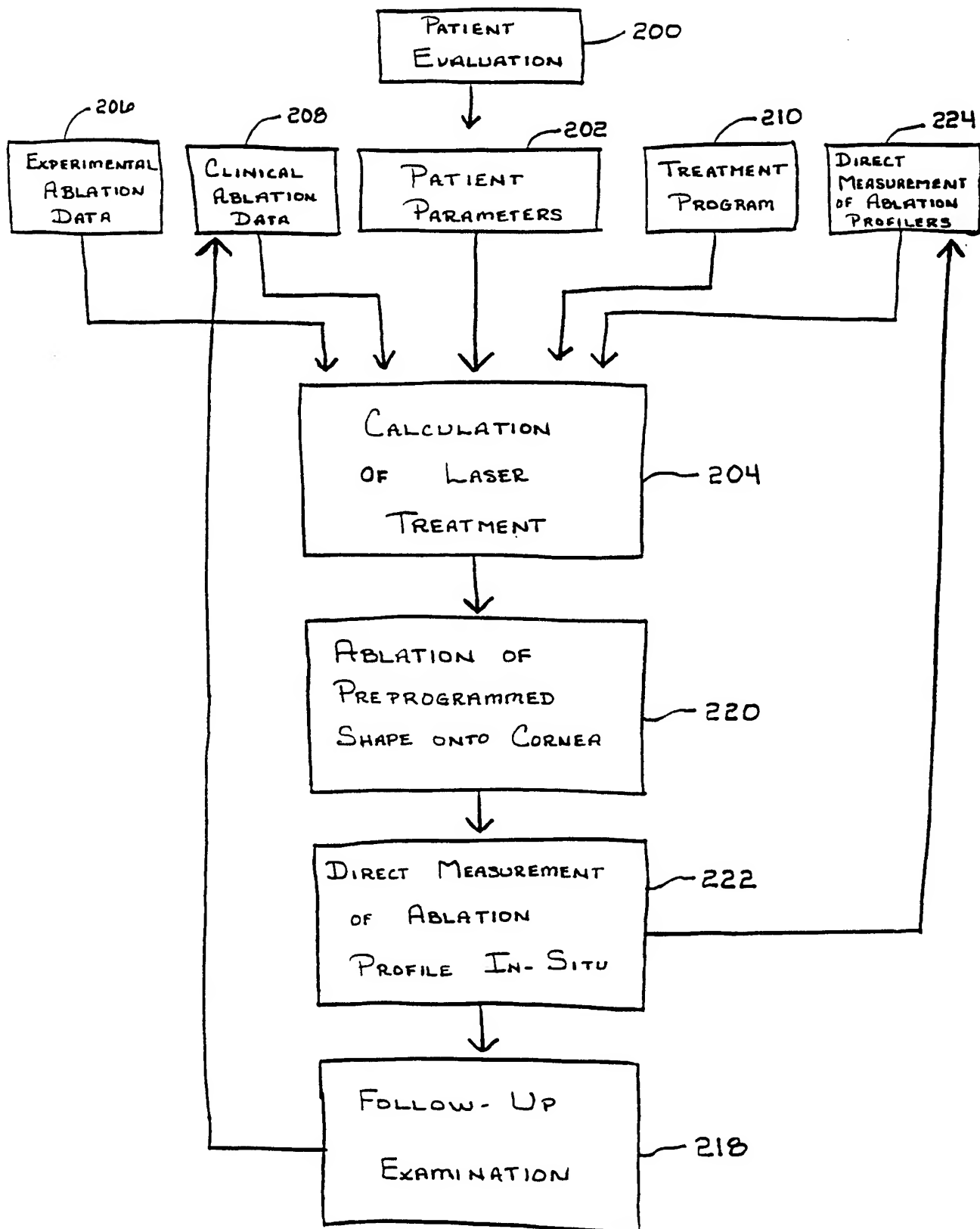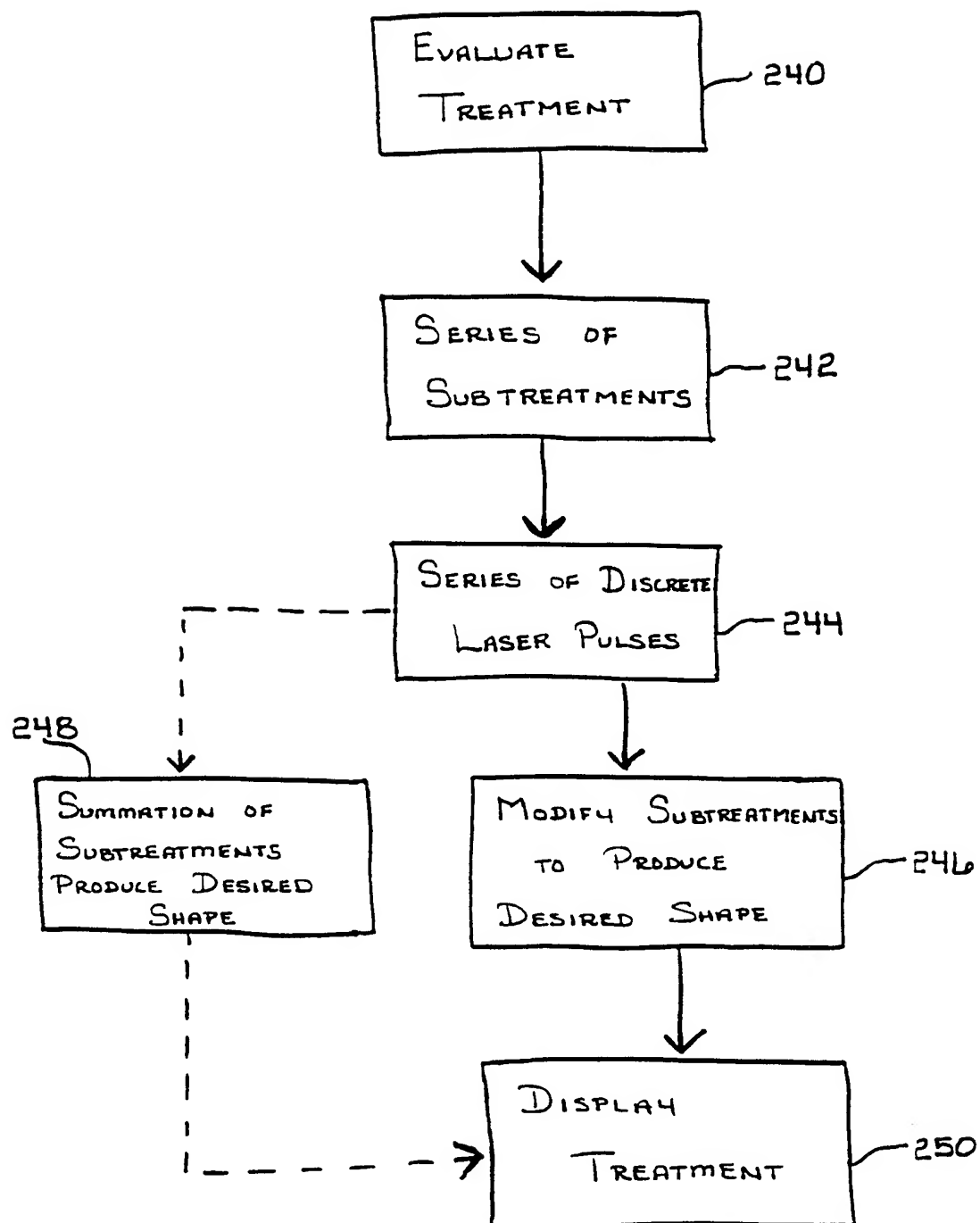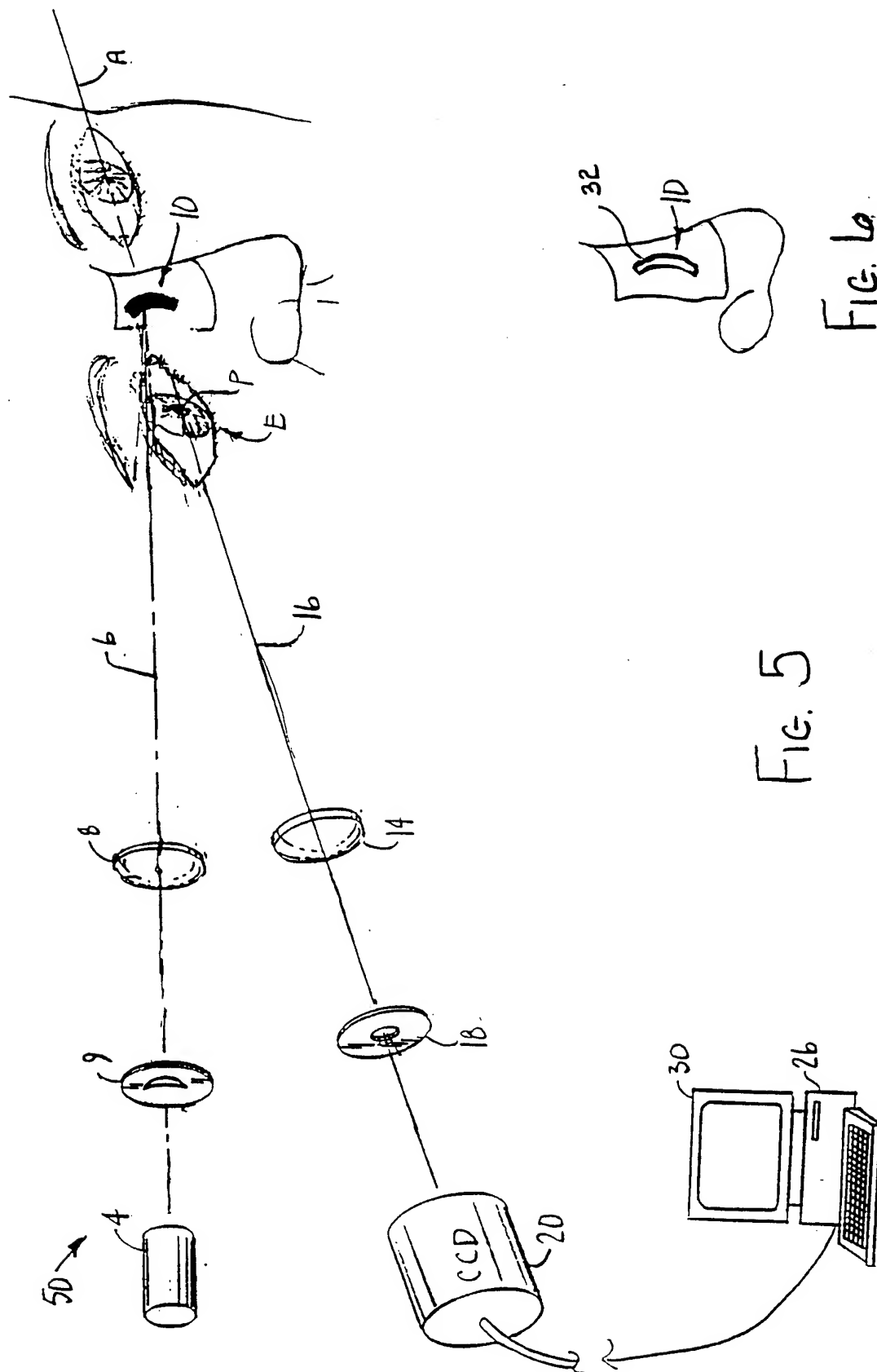
Patient Evaluation ~ 200
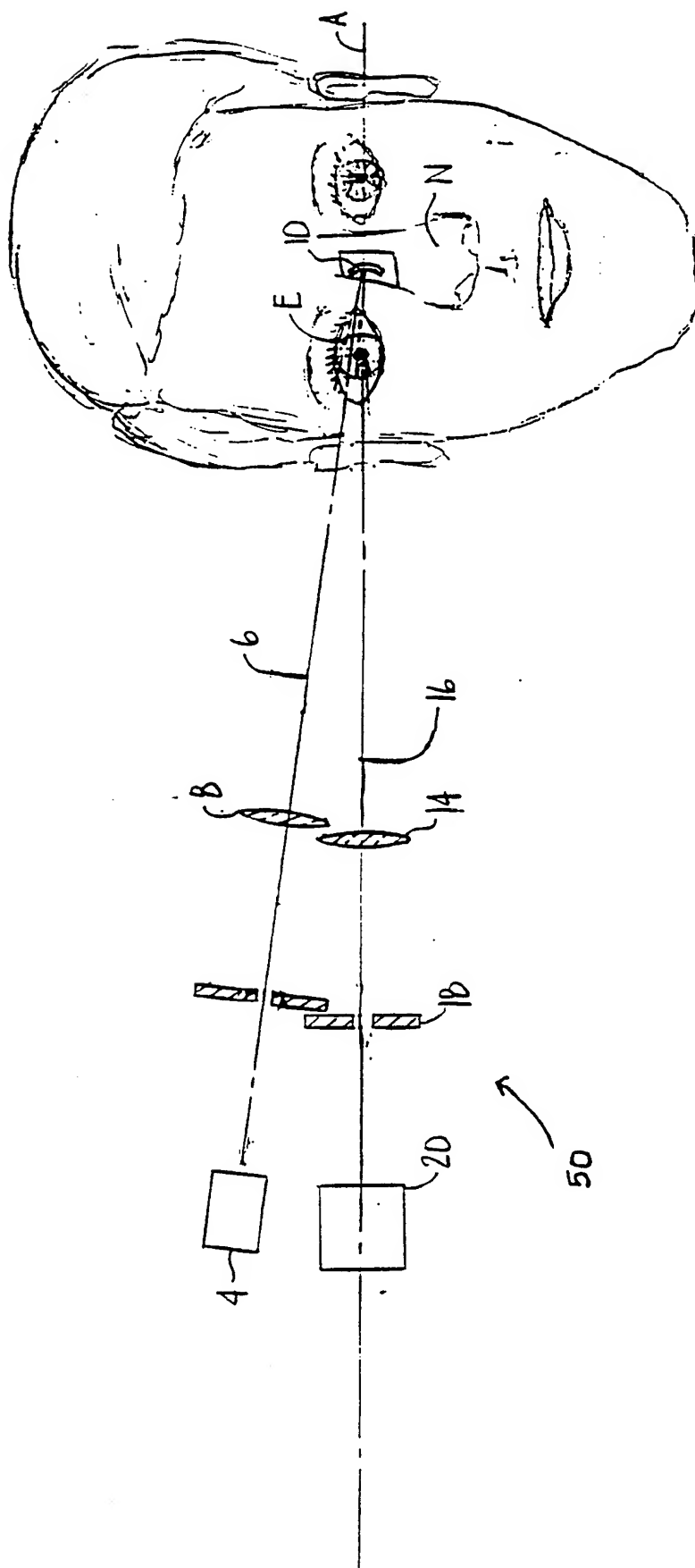
Experimental Ablation Data ~ 206

Clinical Ablation Data ~ 208

Patient Parameters ~ 202

Treatment Program ~ 210

Direct Measurement of Ablation Profilers ~ 224

Calculation of Laser Treatment ~ 204

Ablation of Preprogrammed Shape onto Cornea ~ 220

Direct Measurement of Ablation Profile In-Situ ~ 222
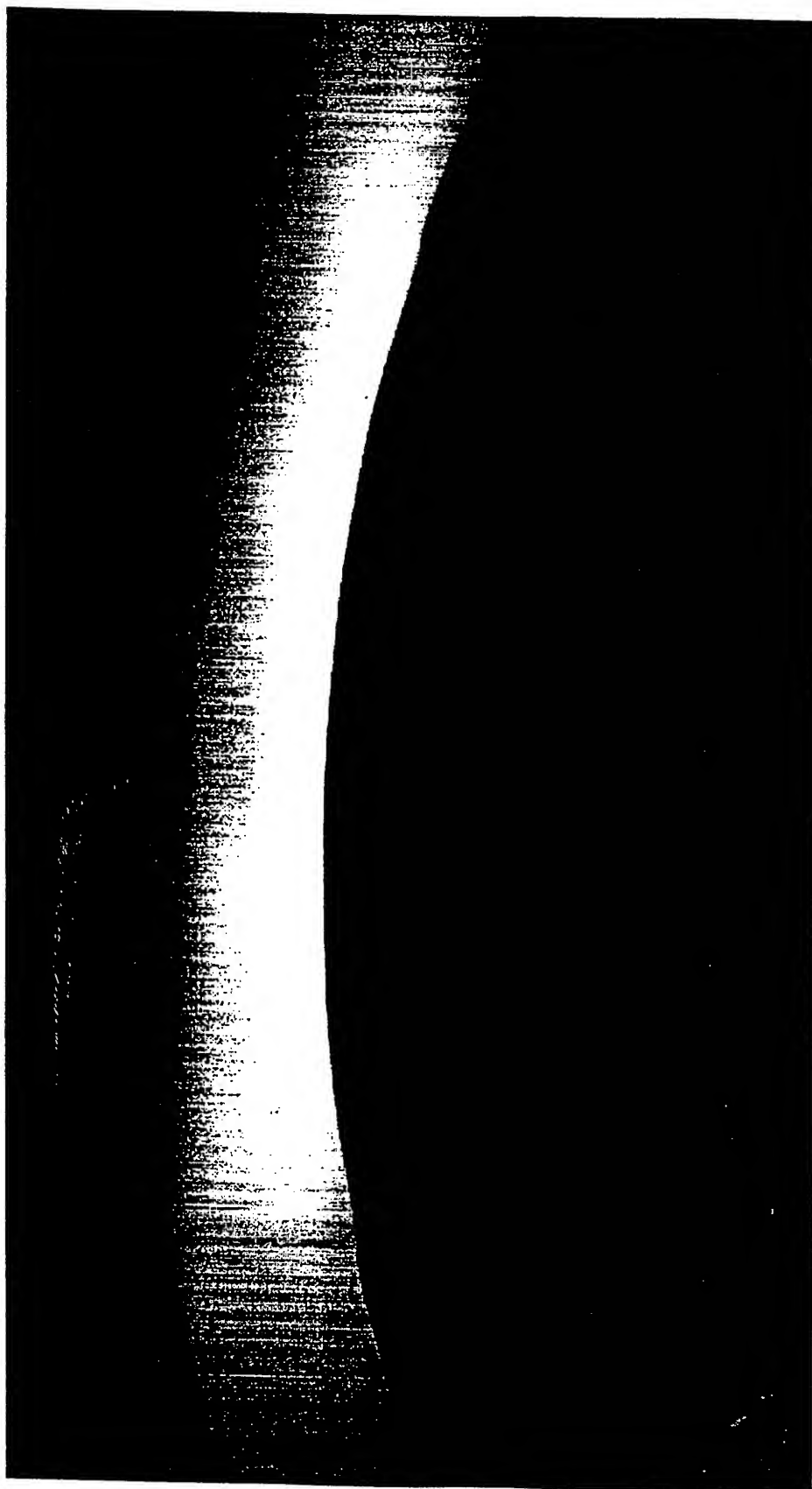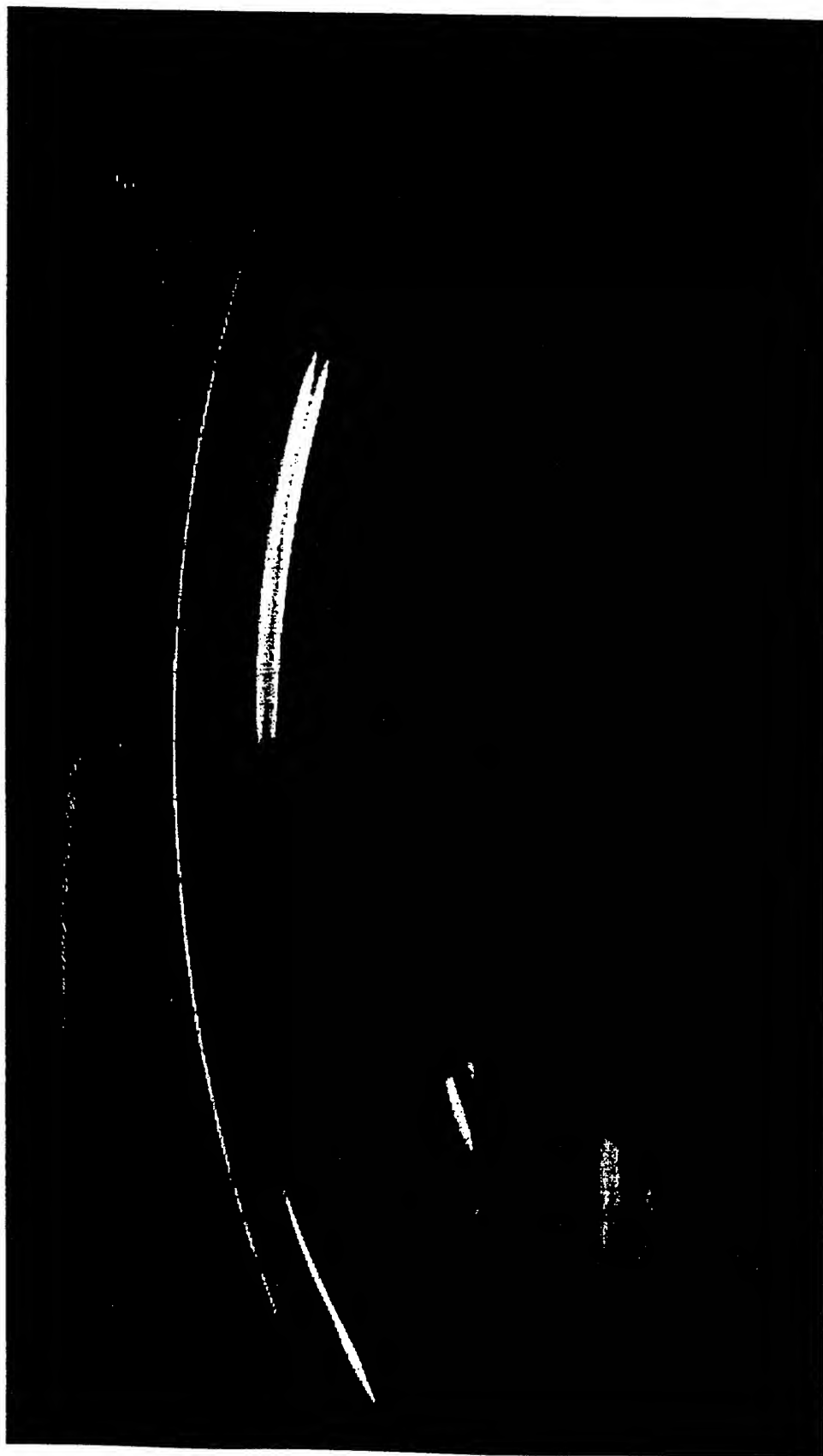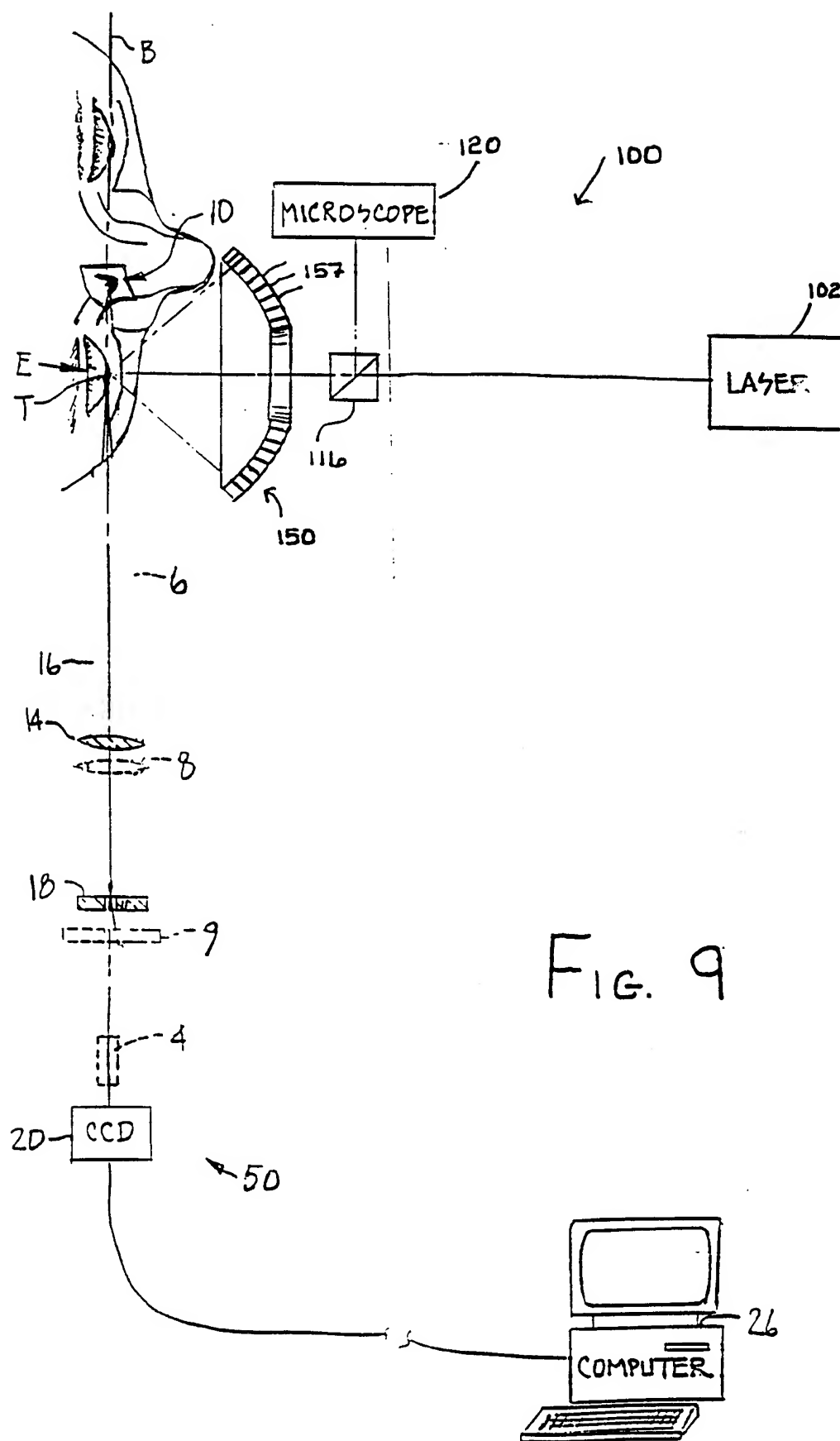
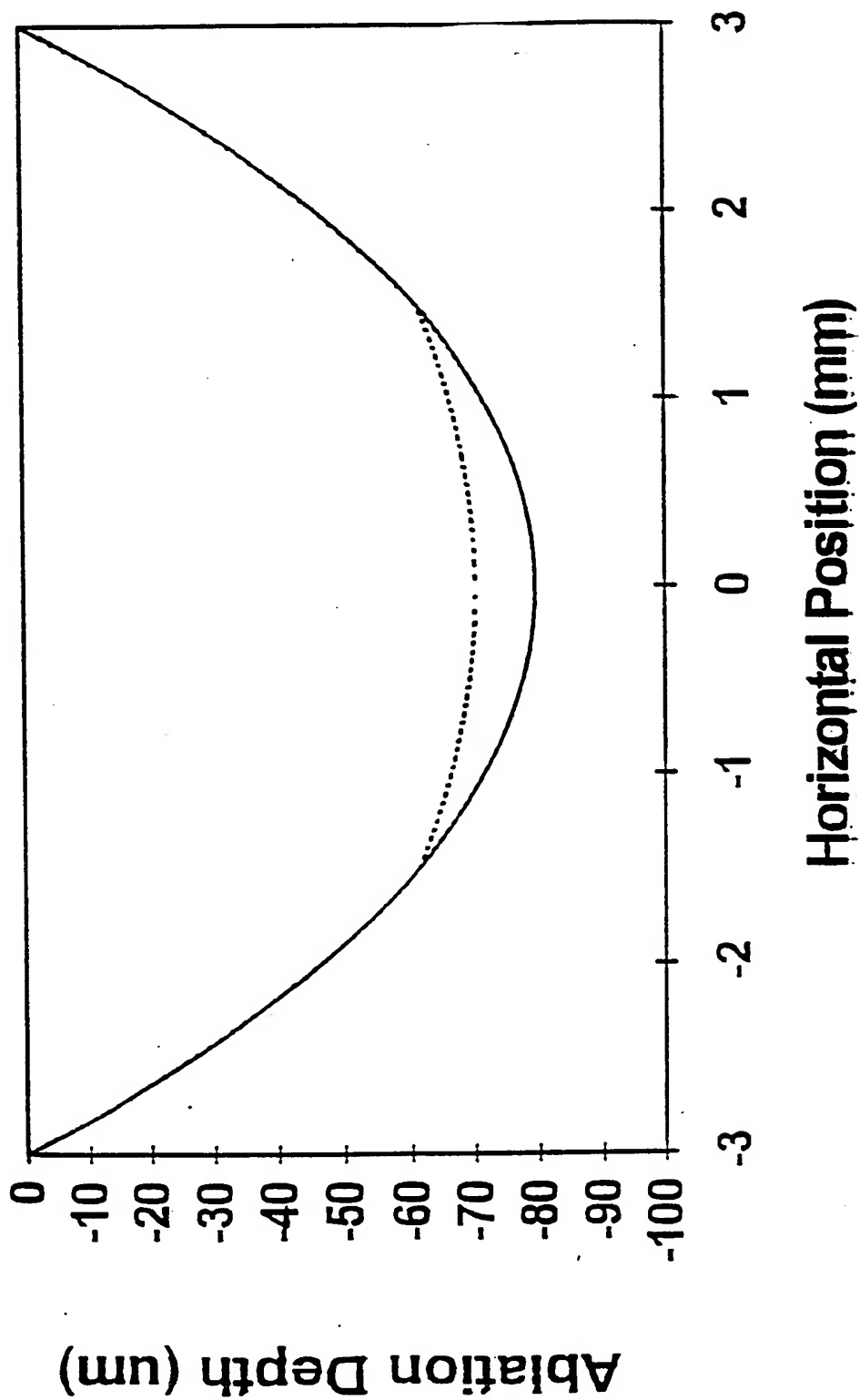Follow-Up Examination ~ 218

FIG. 2

FIG. 3

Fig. 4

Fig. 6

Fig. 5

Fig. 4

Fig. 8

Fig. 9

Fig. 10

FIG. 11

Fig. 12A

FIG. 12B

Fⁱɢ. 13A

Ablation Depth (um)

Horizontal Position (mm)

Fig. 13B

Horizontal Position (mm)

Normalized Ablation Depth
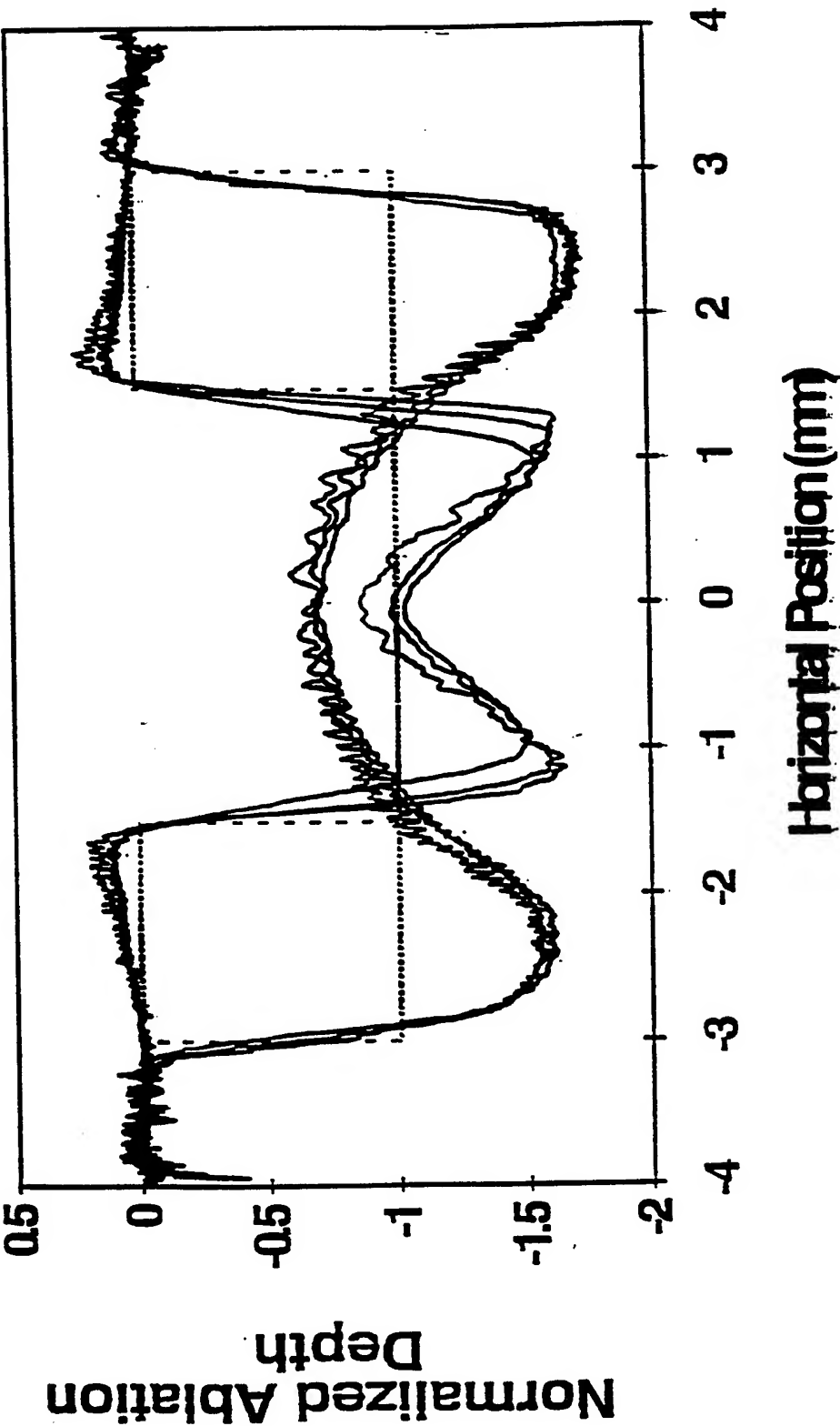
Fig. 14

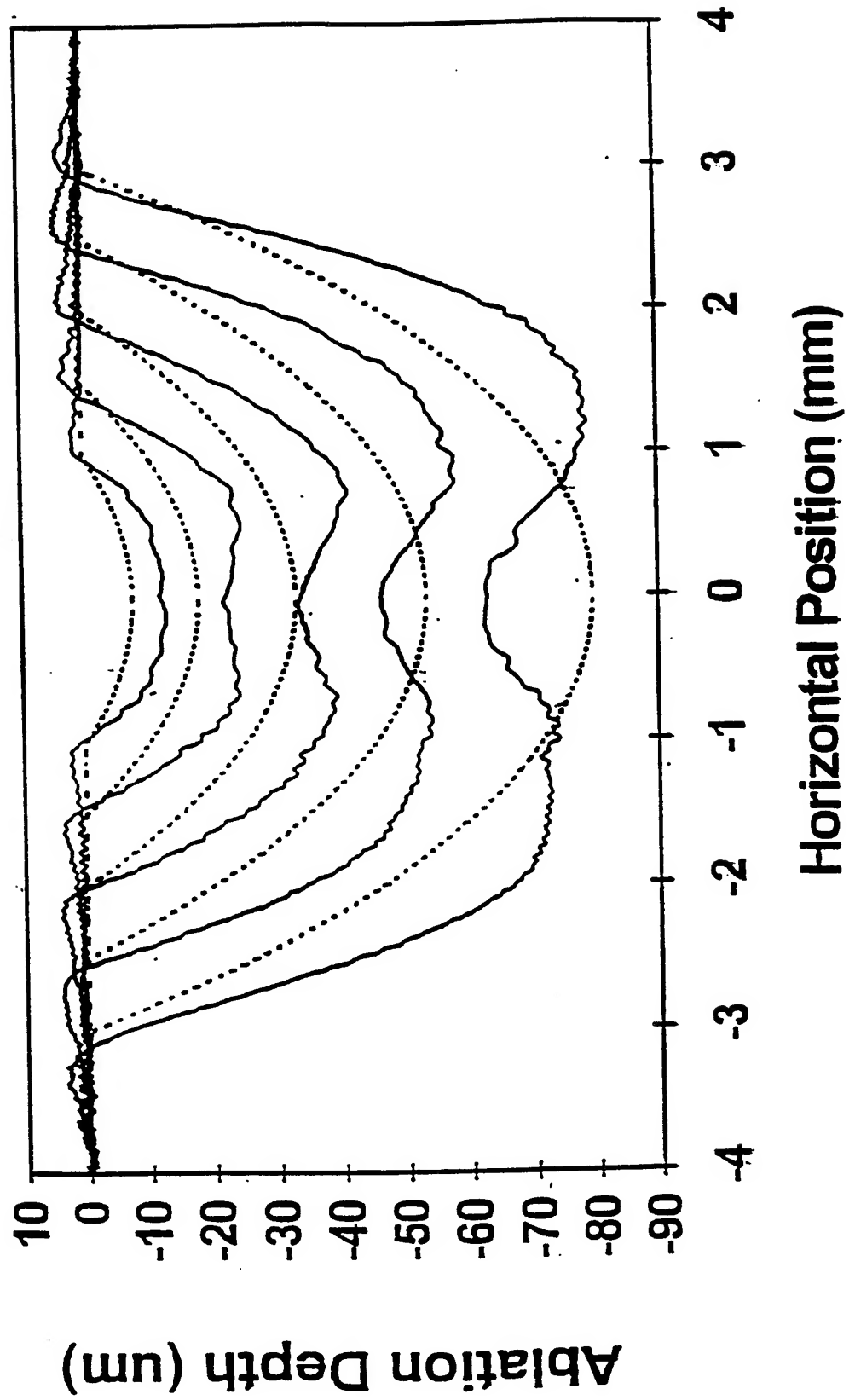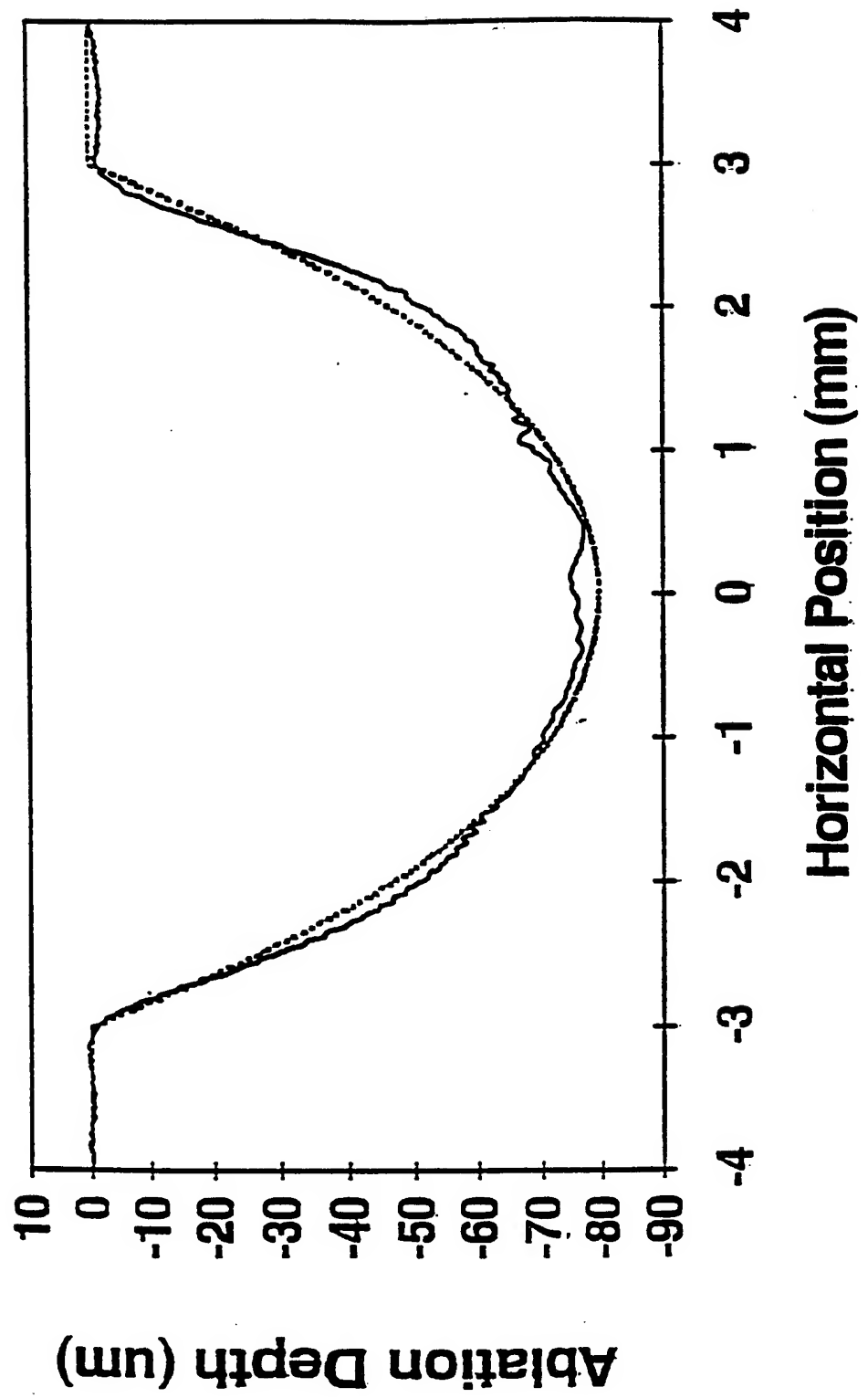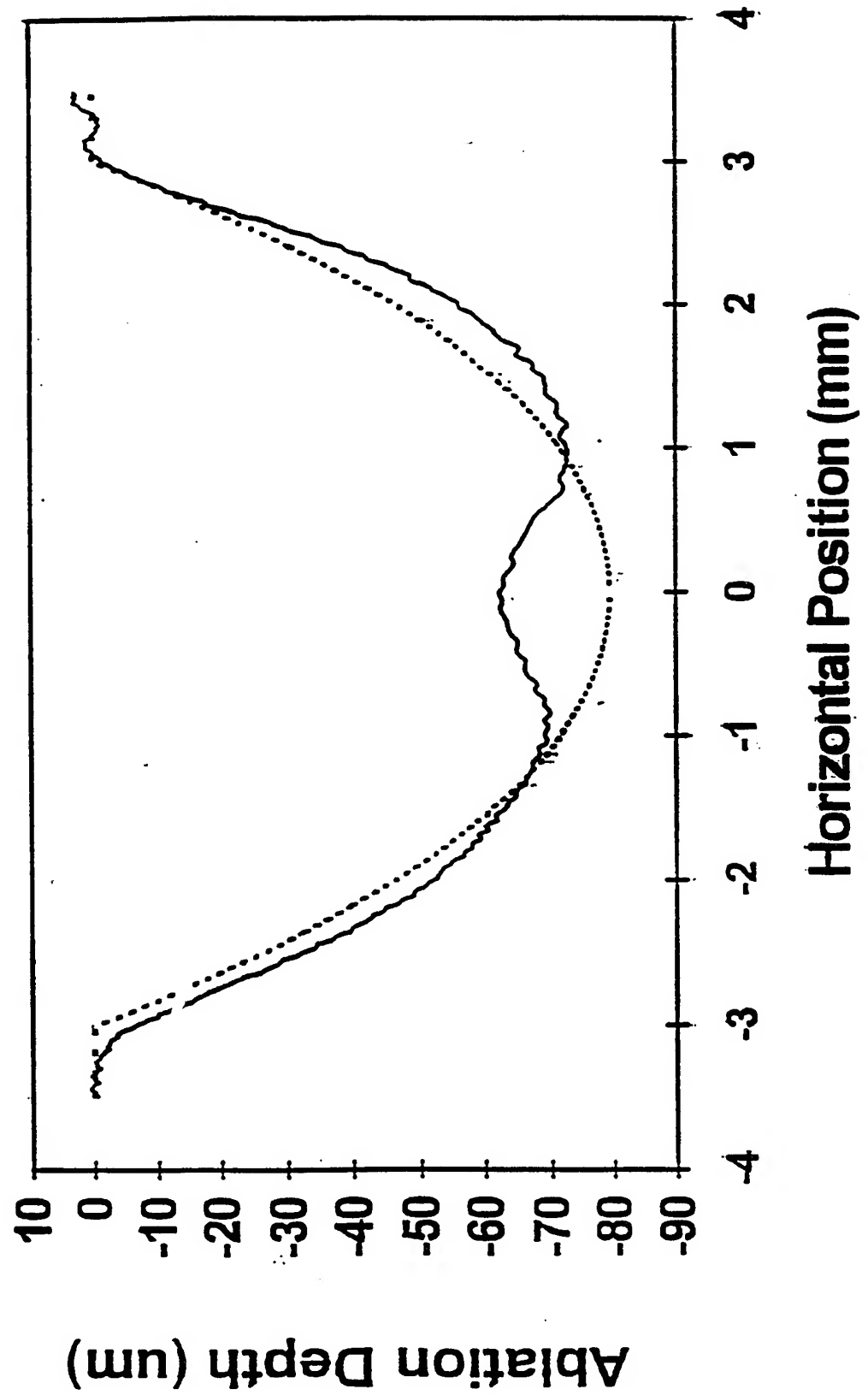Ablation Depth (um) vs Horizontal Position (mm)

FIG. 15

Fig. 16
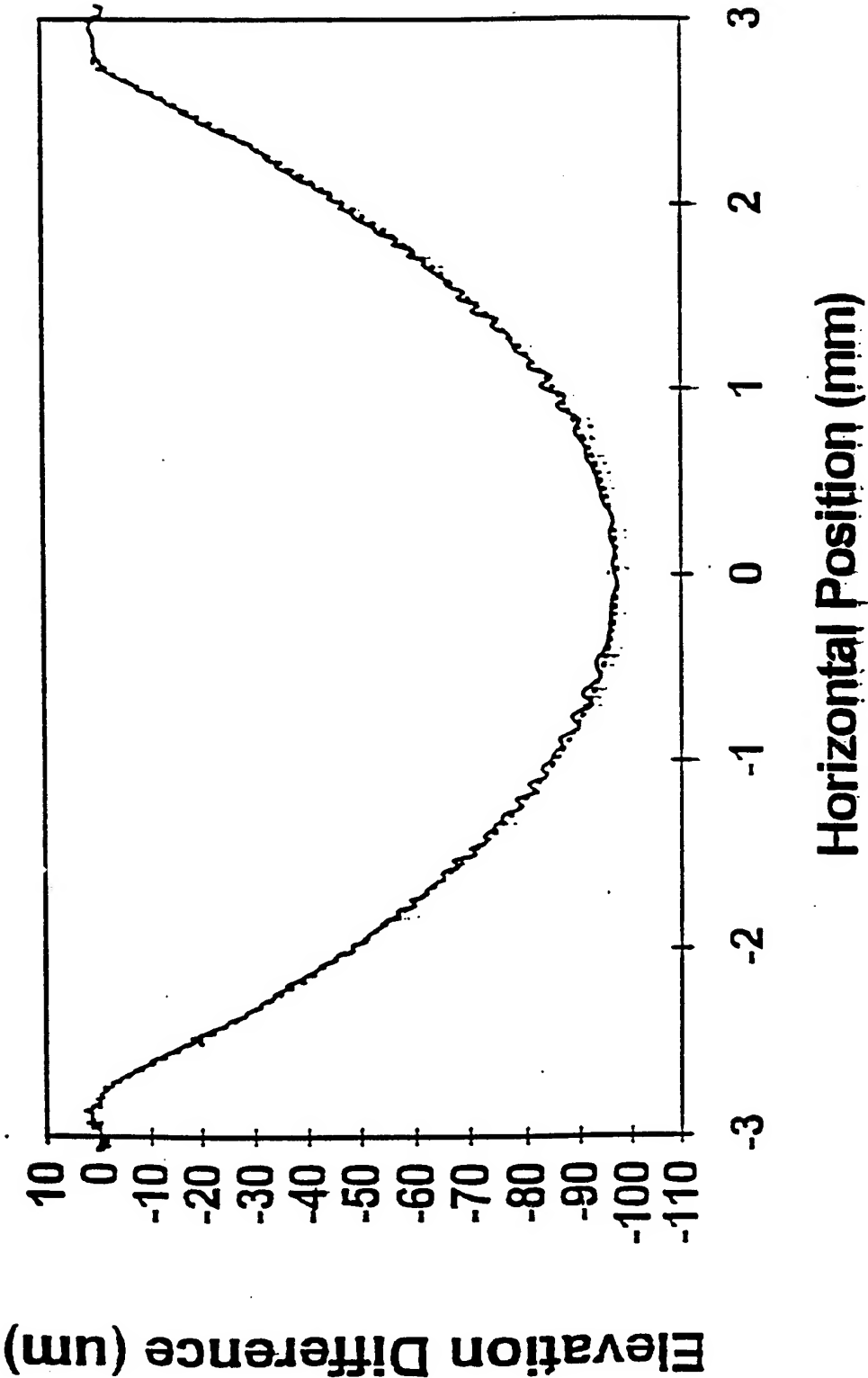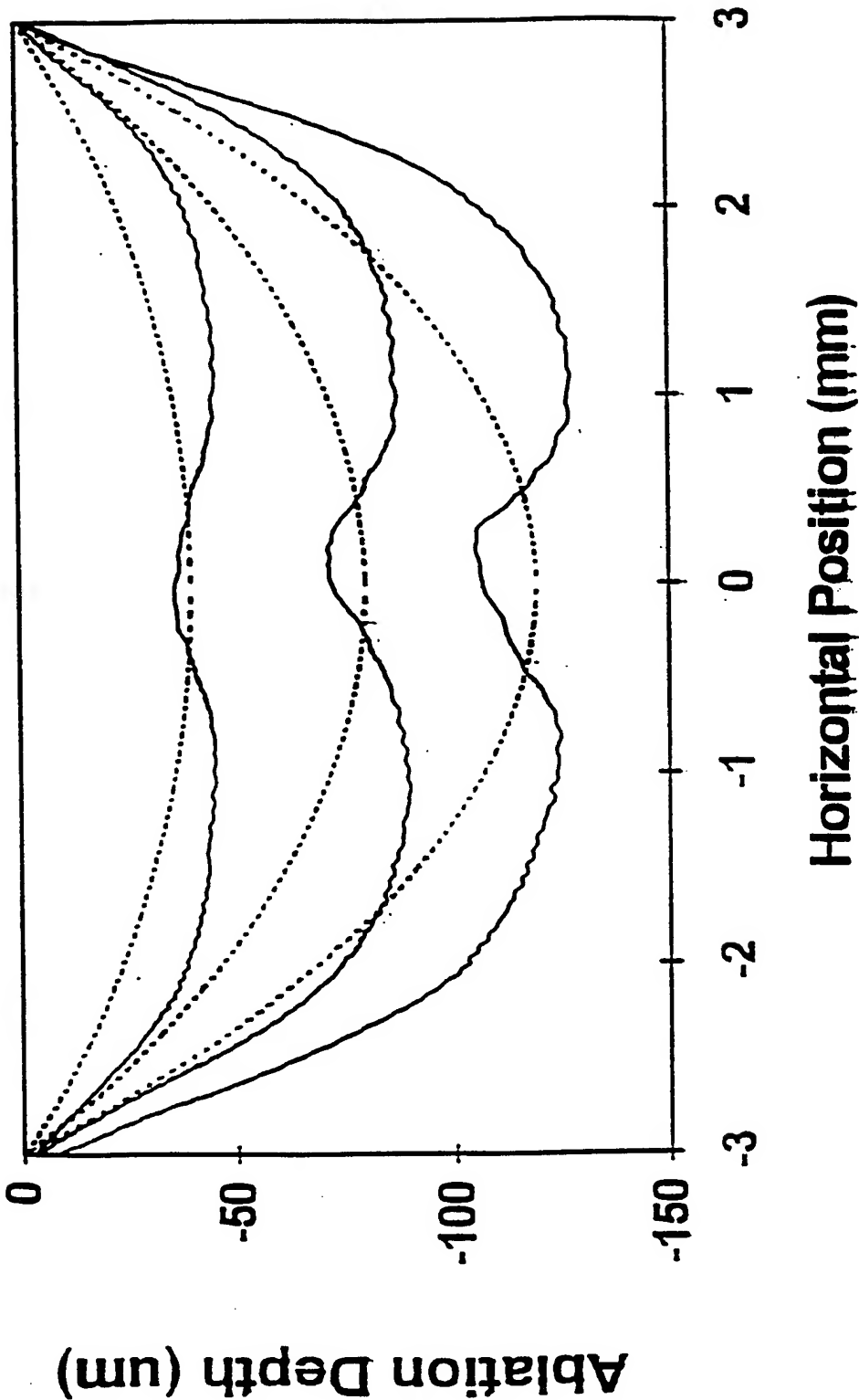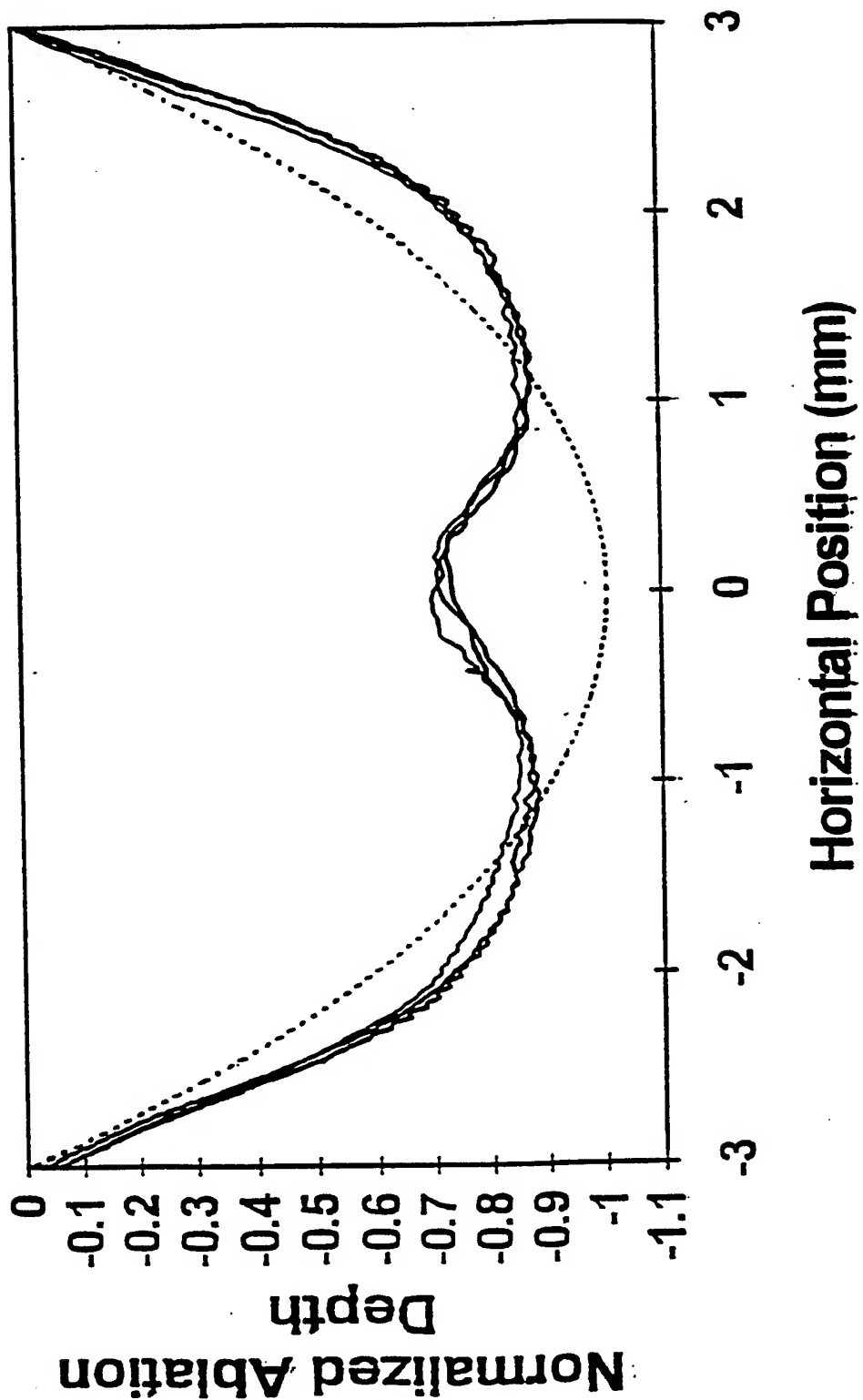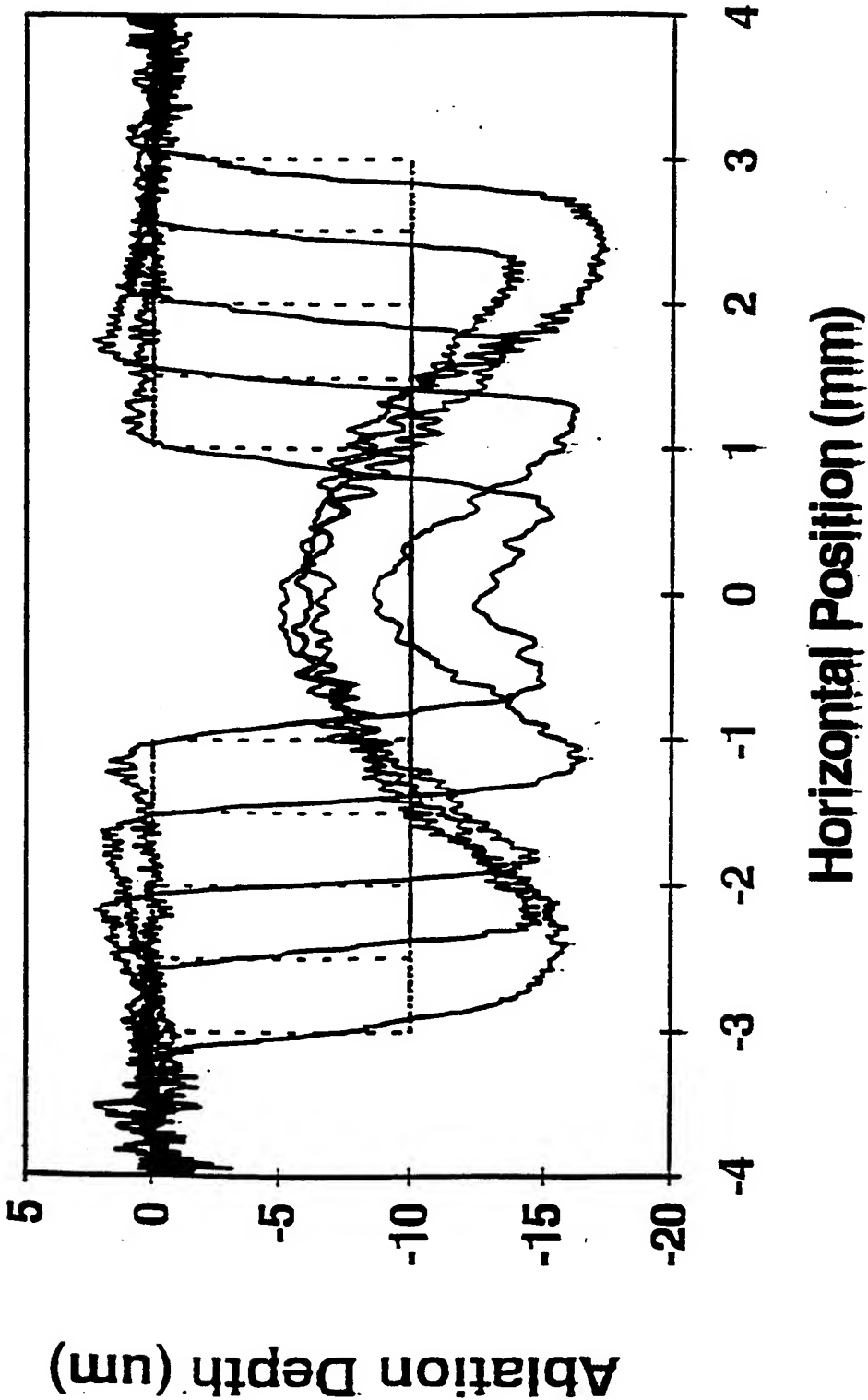
INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/10683

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6)   :A61N 5/06
US CL   :606/5, 10, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/2-6, 10-14

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,911,711 A (TELFAIR et al.) 27 March 1990 (27/03/90), entire document.	1-54

	Further documents are listed in the continuation of Box C.		See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 AUGUST 1998	22 SEP 1998

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